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(12) **United States Patent**
Lintereur et al.

(10) **Patent No.: US 11,998,721 B2**
(45) **Date of Patent: *Jun. 4, 2024**

(54) **CONTINUOUS ANALYTE SENSOR QUALITY MEASURES AND RELATED THERAPY ACTIONS FOR AN AUTOMATED THERAPY DELIVERY SYSTEM**

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(73) Assignee: **MEDTRONIC MINIMED, INC.**, Northridge (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/317,877**

(22) Filed: **May 15, 2023**

(65) **Prior Publication Data**

US 2023/0277768 A1 Sep. 7, 2023

Related U.S. Application Data

(63) Continuation of application No. 16/856,838, filed on Apr. 23, 2020, now Pat. No. 11,690,955.

(51) **Int. Cl.**

A61M 5/172 (2006.01)
G16H 10/40 (2018.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61M 5/1723*** (2013.01); ***G16H 10/40*** (2018.01); ***G16H 20/17*** (2018.01); ***G16H 40/67*** (2018.01);

(Continued)

(58) **Field of Classification Search**

CPC G16H 20/17; G16H 40/67; G16H 10/40; A61M 5/1723; A61M 2205/18;

(Continued)

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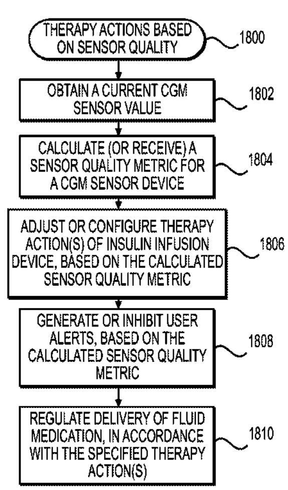
(Continued)

Primary Examiner — Tammara R Peyton
(74) *Attorney, Agent, or Firm* — Weaver Austin Villeneuve & Sampson LLP

(57) **ABSTRACT**

Techniques disclosed herein relate to continuous analyte sensor quality measures. In some embodiments, the techniques may involve obtaining a current sensor-generated value that is indicative of a physiological characteristic of a user of a medical device, the current sensor-generated value produced in response to operation of a continuous analyte sensor device. The techniques may further involve obtaining a sensor quality metric that indicates accuracy of the current sensor-generated value. The techniques may further involve causing, in response to obtaining the sensor quality metric, configuration of a quality-specific operating mode of the medical device, the quality-specific operating mode comprising separate regulation of basal and bolus deliveries of a fluid medication based on the obtained sensor quality metric. The techniques may further involve causing regulation of

(Continued)



fluid medication delivery from the medical device, in accordance with the current sensor-generated value and the quality-specific operating mode of the medical device.

20 Claims, 18 Drawing Sheets

(51) **Int. Cl.**
G16H 20/17 (2018.01)
G16H 40/67 (2018.01)

(52) **U.S. Cl.**
CPC . *A61M 2205/18* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/50* (2013.01); *A61M 2205/502* (2013.01); *A61M 2205/505* (2013.01); *A61M 2205/52* (2013.01); *A61M 2205/581* (2013.01); *A61M 2205/582* (2013.01); *A61M 2205/583* (2013.01); *A61M 2205/702* (2013.01); *A61M 2230/201* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2205/502; A61M 2205/52; A61M 2205/702; A61M 2230/201
See application file for complete search history.

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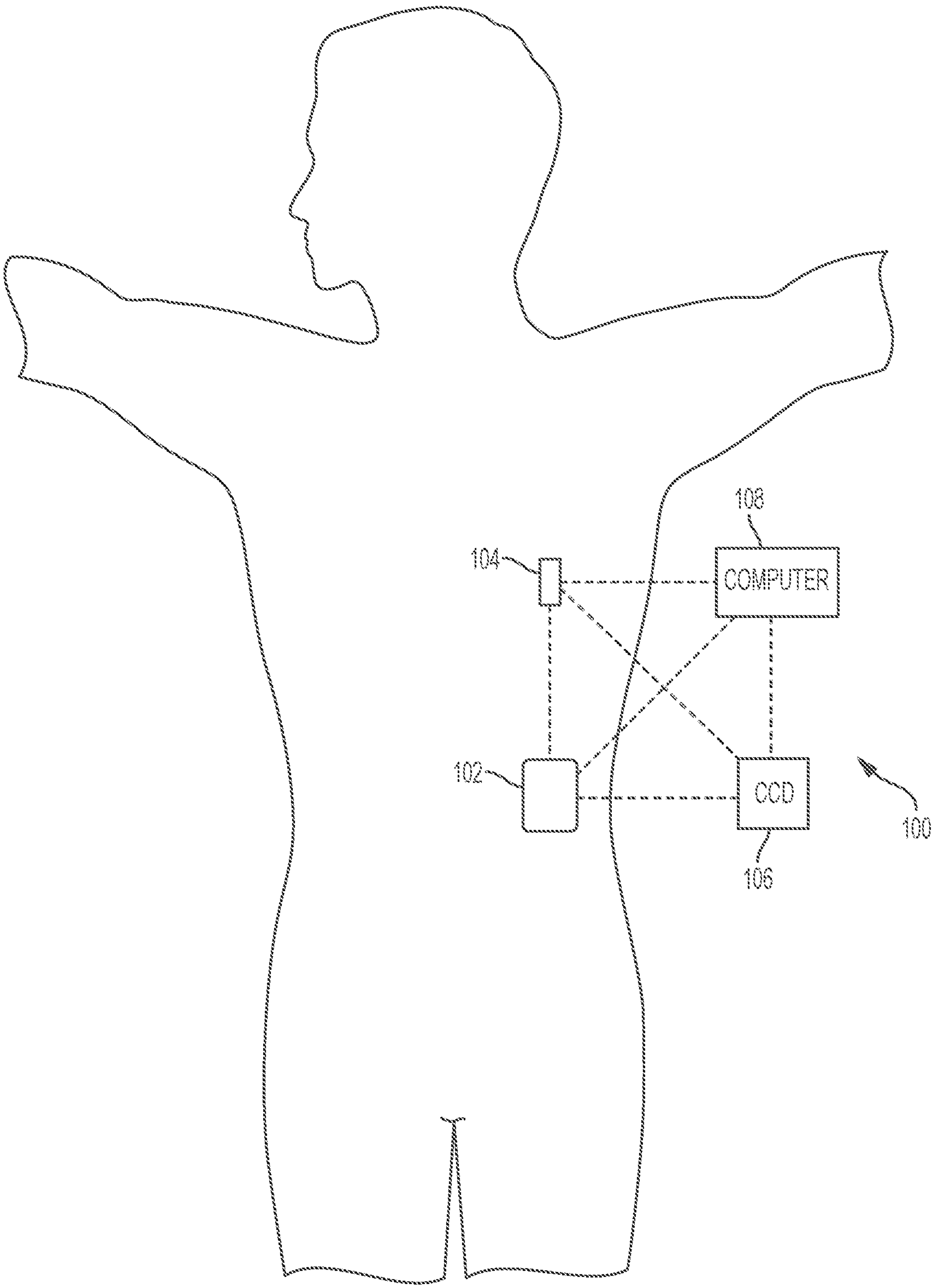

FIG. 1

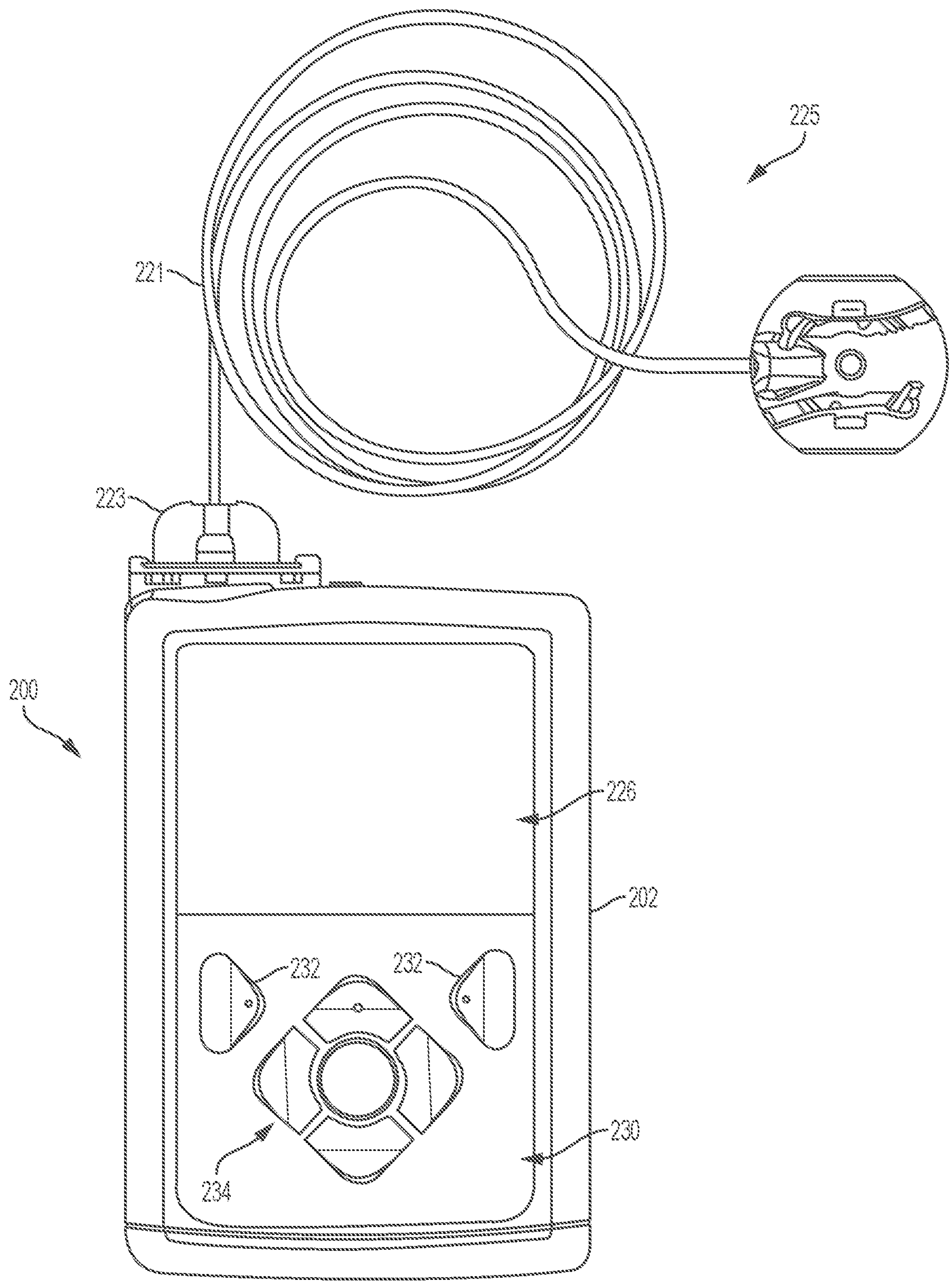

FIG. 2

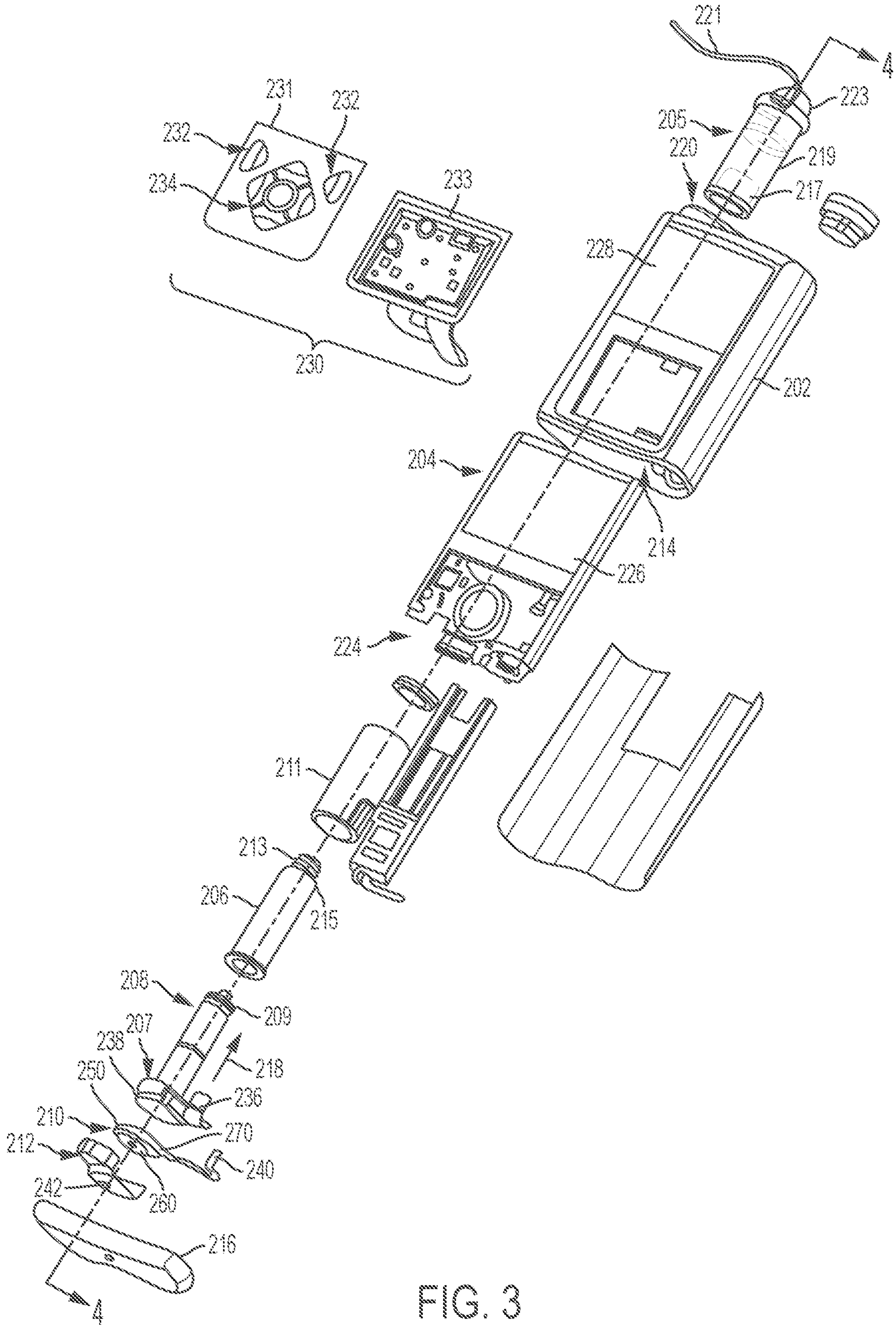
221
4
223
205
220
219
217
231
232
232
234
233
228
230
202
204
214
226
224
211
213
206
215
208
209
207
238
218
250
236
210
270
212
240
242
260
216
4

FIG. 3

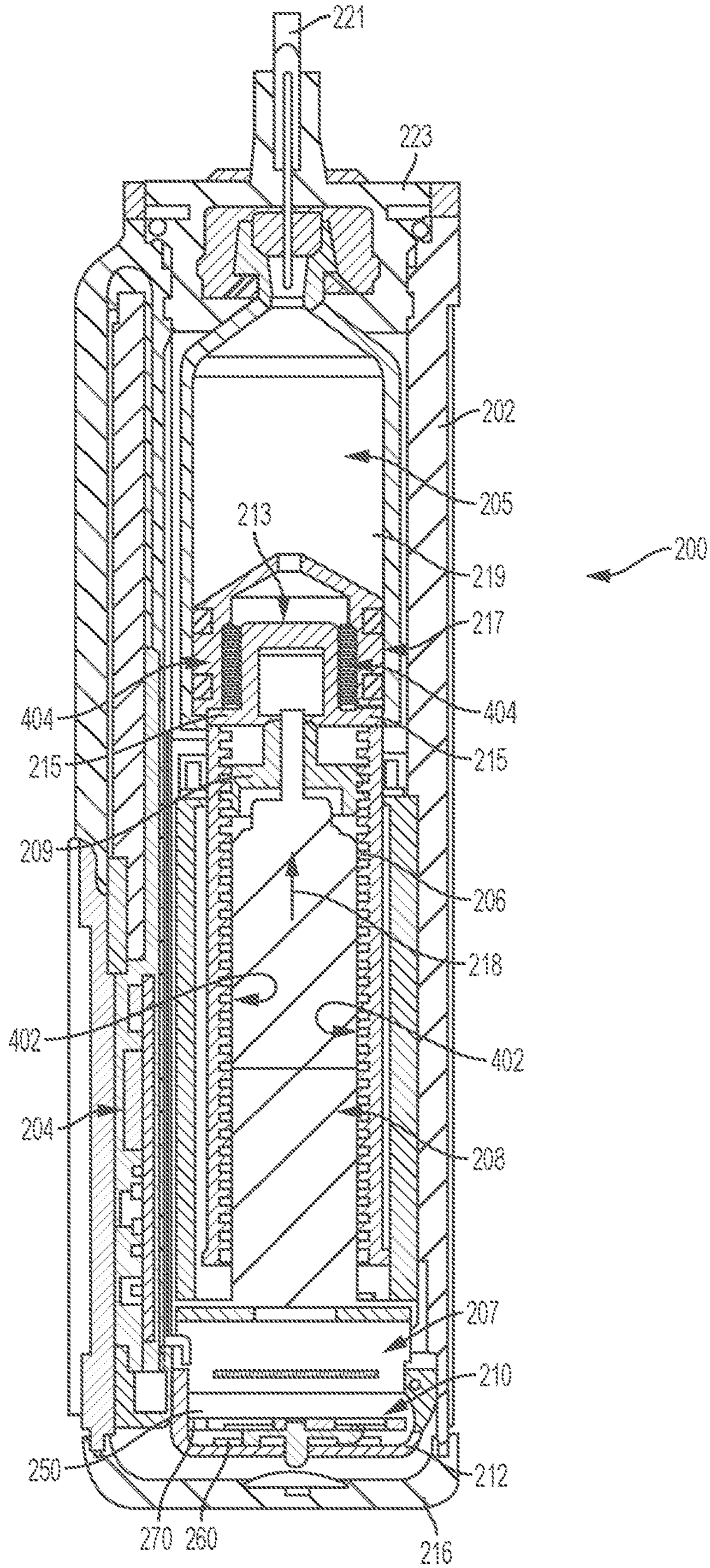
221
223
202
205
213
219
200
217
404
404
215
215
209
206
218
402
402
204
208
207
210
250
212
270
260
216

FIG. 4

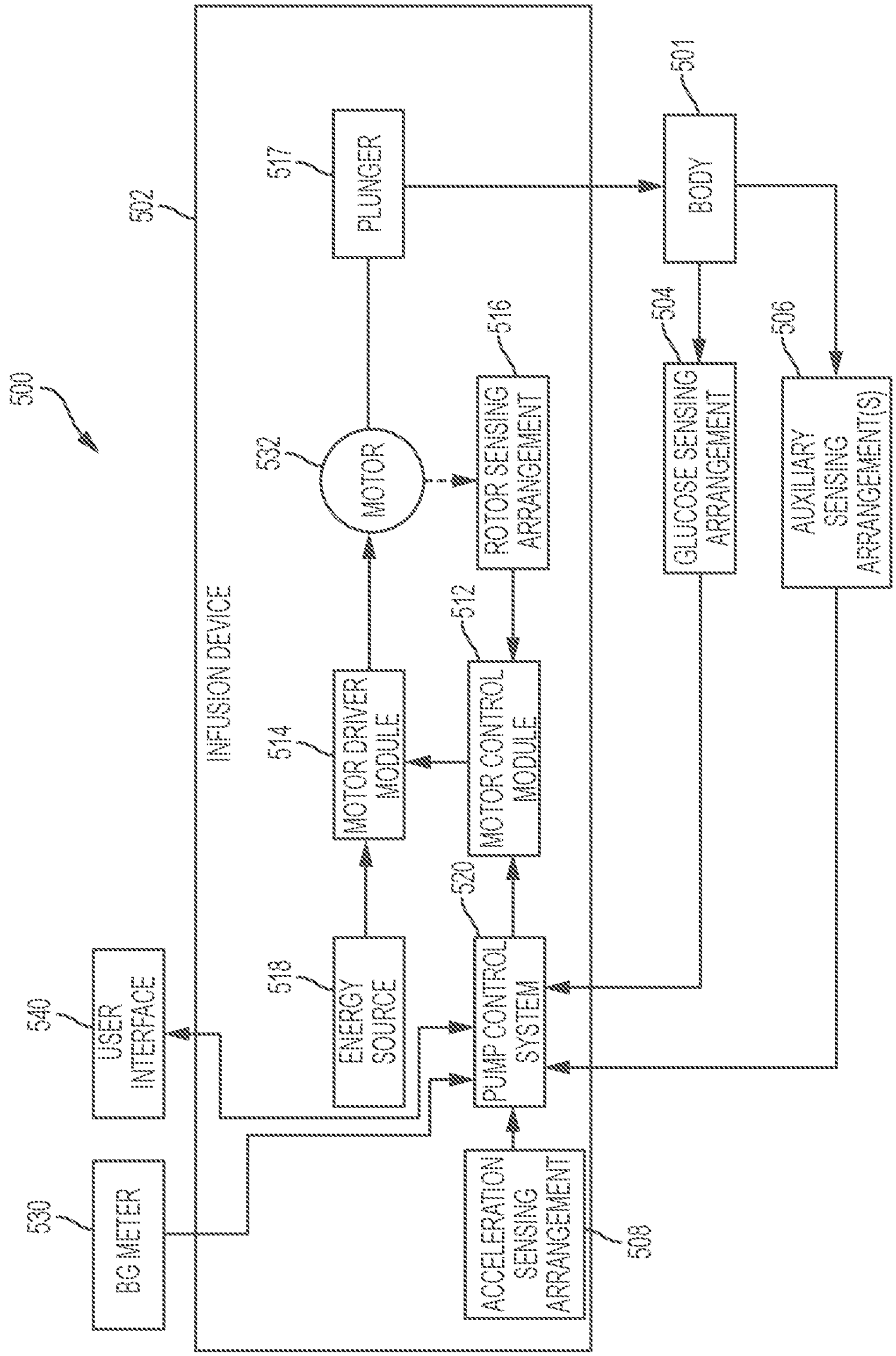
500
502
INFUSION DEVICE
517
PLUNGER
532
MOTOR
516
ROTOR SENSING ARRANGEMENT
514
MOTOR DRIVER MODULE
512
MOTOR CONTROL MODULE
518
ENERGY SOURCE
520
PUMP CONTROL SYSTEM
508
ACCELERATION SENSING ARRANGEMENT
540
USER INTERFACE
530
BG METER
501
BODY
504
GLUCOSE SENSING ARRANGEMENT
506
AUXILIARY SENSING ARRANGEMENT(S)

FIG. 5

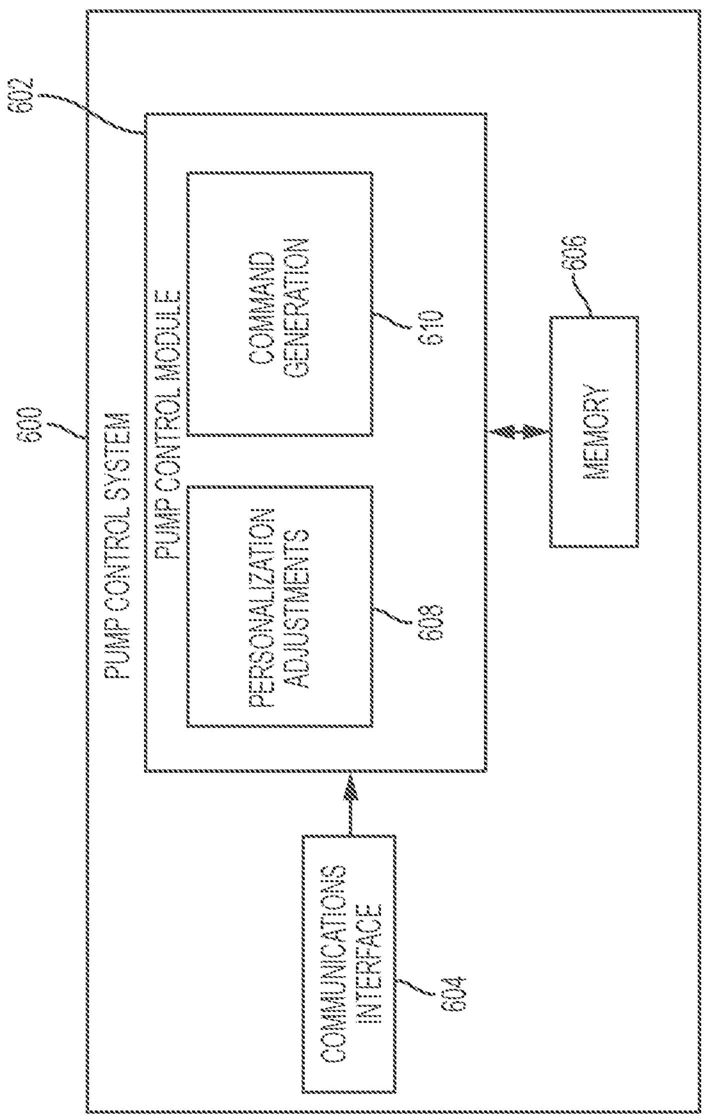
600
PUMP CONTROL SYSTEM
602
PUMP CONTROL MODULE
PERSONALIZATION ADJUSTMENTS
608
COMMAND GENERATION
610
MEMORY
606
COMMUNICATIONS INTERFACE
604

FIG. 6

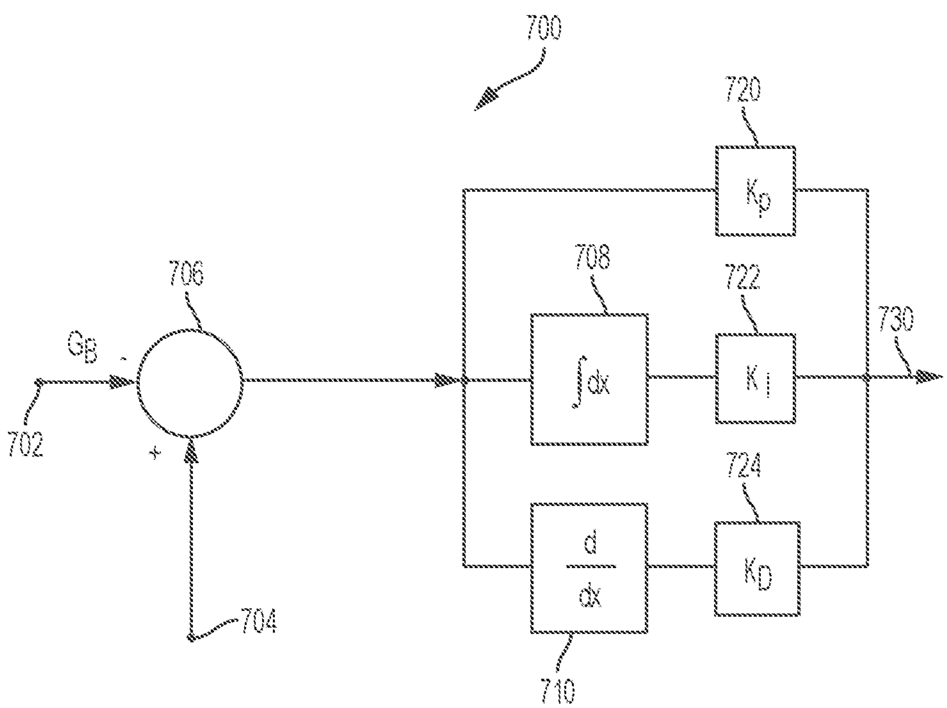

FIG. 7

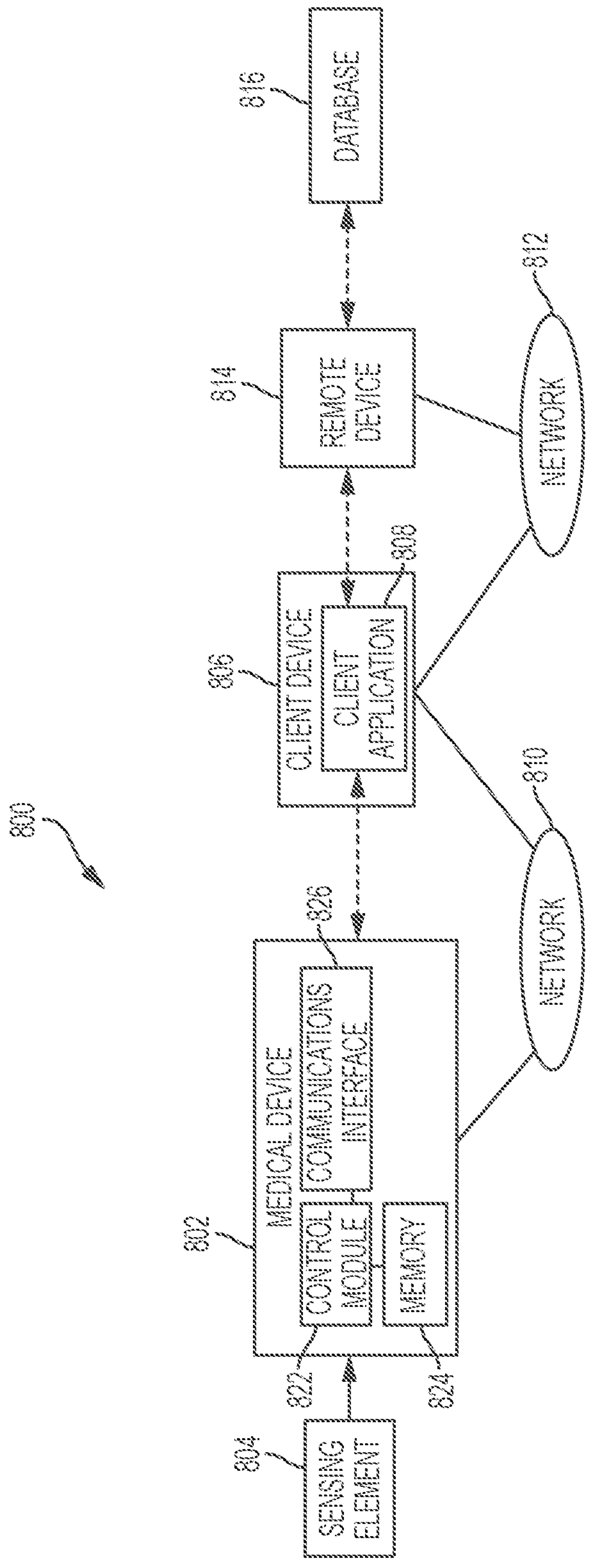
800
DATABASE
816
REMOTE DEVICE
814
NETWORK
812
CLIENT DEVICE
806
CLIENT APPLICATION
808
NETWORK
810
MEDICAL DEVICE
802
COMMUNICATIONS INTERFACE
826
CONTROL MODULE
822
MEMORY
824
SENSING ELEMENT
804

FIG. 8

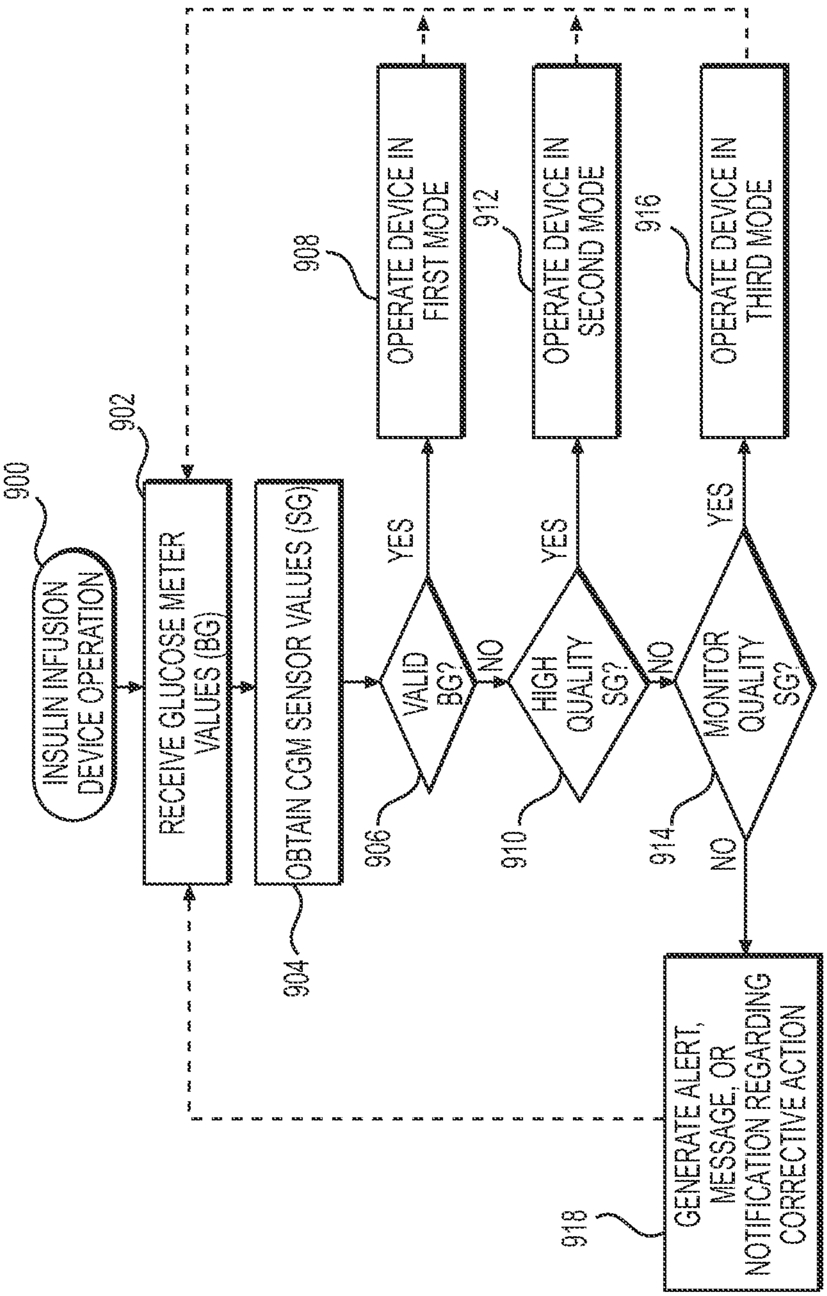
900
INSULIN INFUSION DEVICE OPERATION
902
RECEIVE GLUCOSE METER VALUES (BG)
904
OBTAIN CGM SENSOR VALUES (SG)
906
VALID BG?
YES
NO
908
OPERATE DEVICE IN FIRST MODE
910
HIGH QUALITY SG?
YES
NO
912
OPERATE DEVICE IN SECOND MODE
914
MONITOR QUALITY SG?
YES
NO
916
OPERATE DEVICE IN THIRD MODE
918
GENERATE ALERT, MESSAGE, OR NOTIFICATION REGARDING CORRECTIVE ACTION

FIG. 9

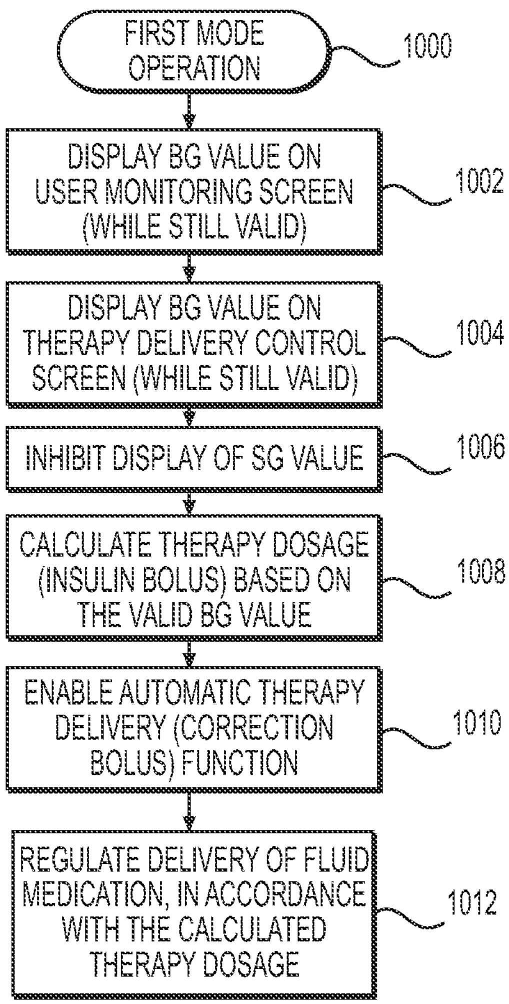
FIRST MODE OPERATION
1000
DISPLAY BG VALUE ON USER MONITORING SCREEN (WHILE STILL VALID)
1002
DISPLAY BG VALUE ON THERAPY DELIVERY CONTROL SCREEN (WHILE STILL VALID)
1004
INHIBIT DISPLAY OF SG VALUE
1006
CALCULATE THERAPY DOSAGE (INSULIN BOLUS) BASED ON THE VALID BG VALUE
1008
ENABLE AUTOMATIC THERAPY DELIVERY (CORRECTION BOLUS) FUNCTION
1010
REGULATE DELIVERY OF FLUID MEDICATION, IN ACCORDANCE WITH THE CALCULATED THERAPY DOSAGE
1012

FIG. 10

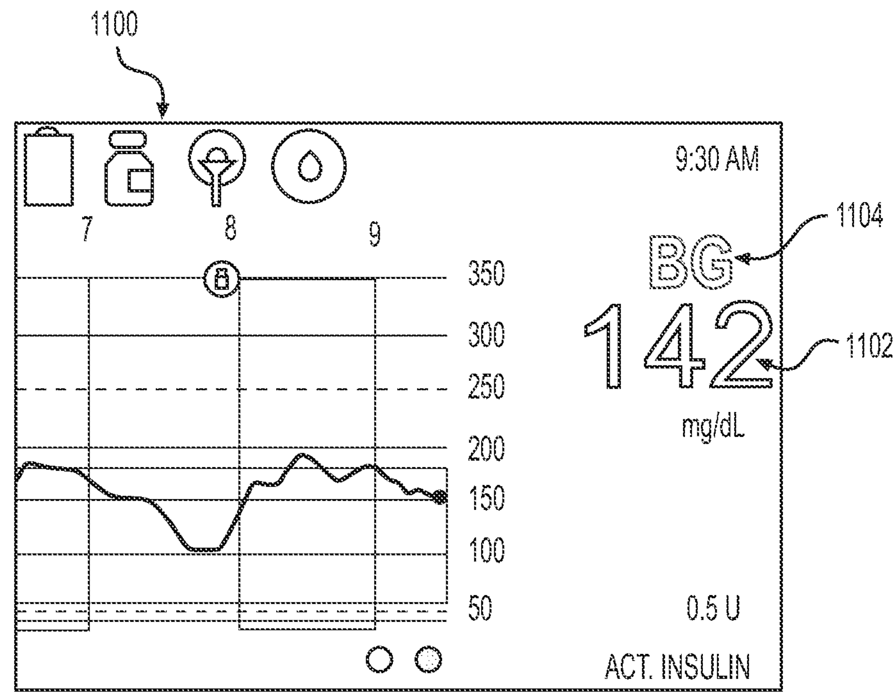
1100
9:30 AM
7
8
9
1104
BG
142
1102
mg/dL
350
300
250
200
150
100
50
0.5 U
ACT. INSULIN

FIG. 11

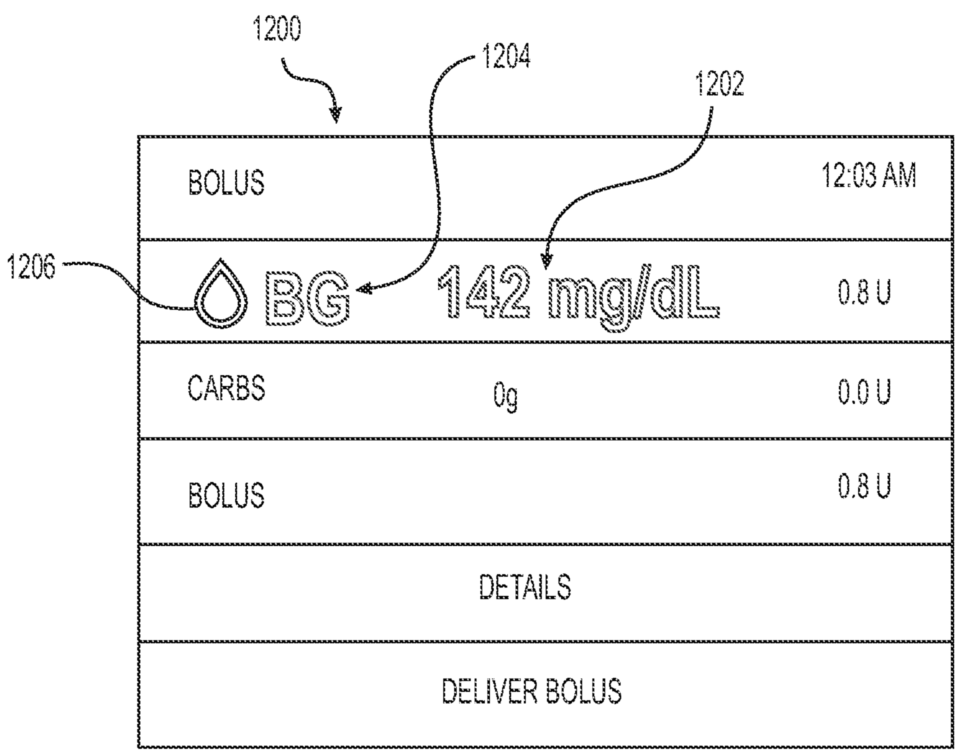
1200
1204
1202
BOLUS
12:03 AM
1206
BG
142 mg/dL
0.8 U
CARBS
0g
0.0 U
BOLUS
0.8 U
DETAILS
DELIVER BOLUS

FIG. 12

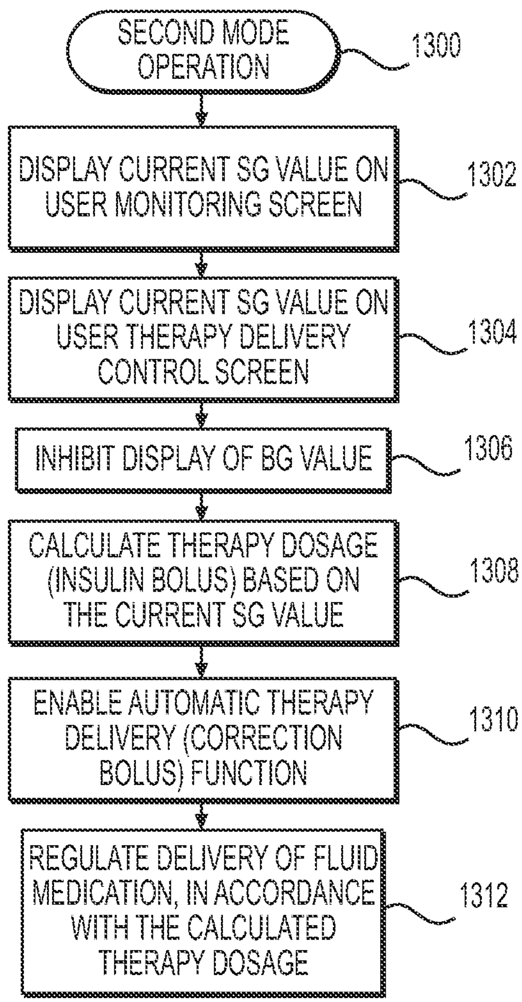
SECOND MODE OPERATION
1300
DISPLAY CURRENT SG VALUE ON USER MONITORING SCREEN
1302
DISPLAY CURRENT SG VALUE ON USER THERAPY DELIVERY CONTROL SCREEN
1304
INHIBIT DISPLAY OF BG VALUE
1306
CALCULATE THERAPY DOSAGE (INSULIN BOLUS) BASED ON THE CURRENT SG VALUE
1308
ENABLE AUTOMATIC THERAPY DELIVERY (CORRECTION BOLUS) FUNCTION
1310
REGULATE DELIVERY OF FLUID MEDICATION, IN ACCORDANCE WITH THE CALCULATED THERAPY DOSAGE
1312

FIG. 13

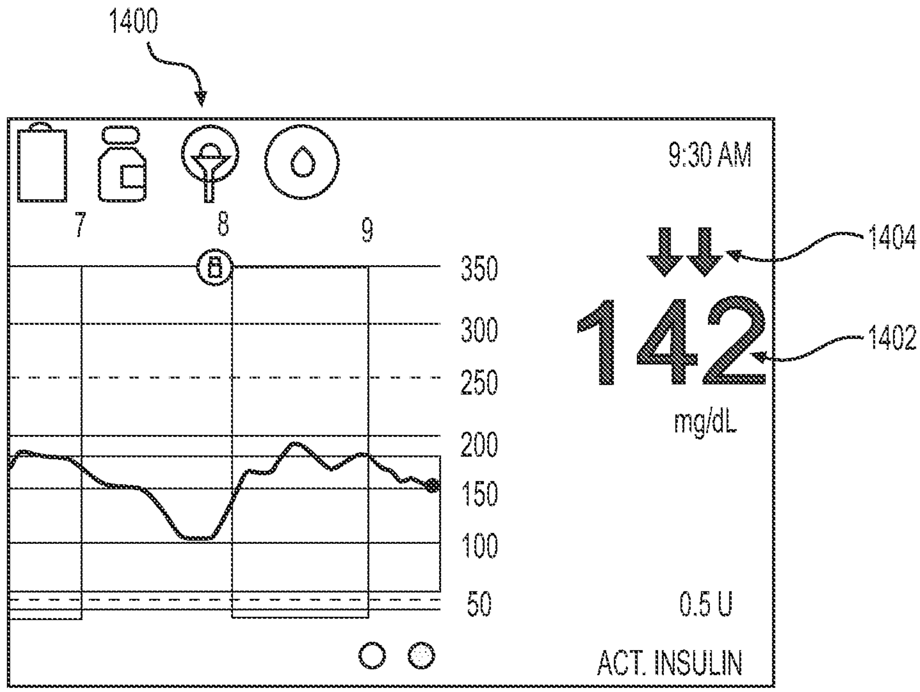
1400
9:30 AM
7
8
9
350
300
250
200
150
100
50
1404
142
1402
mg/dL
0.5 U
ACT. INSULIN

FIG. 14

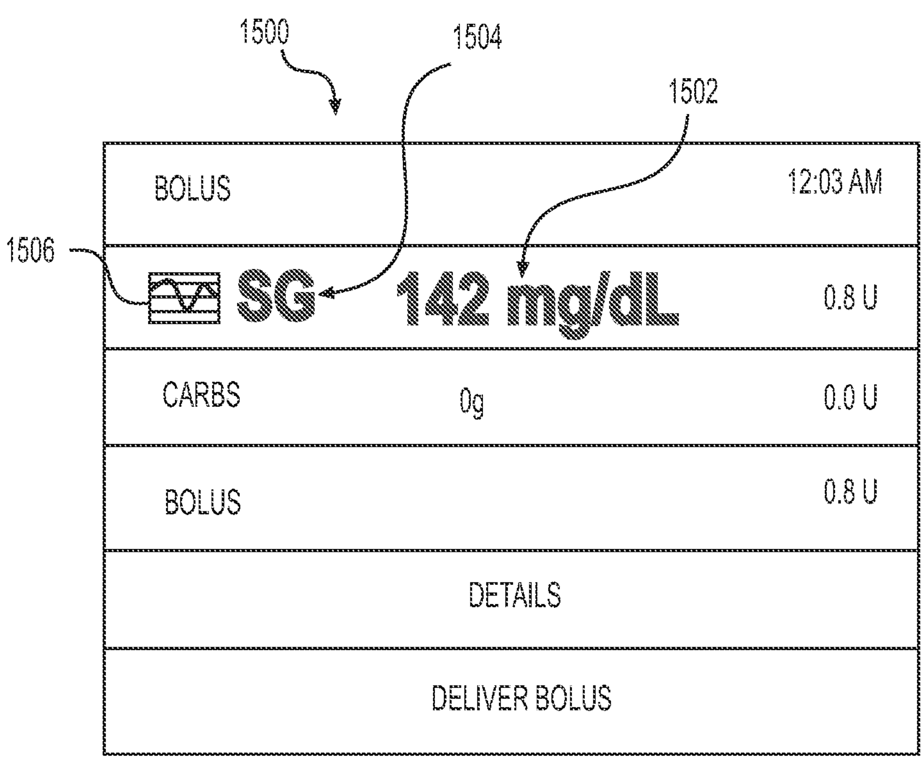
1500
1504
1502
BOLUS
12:03 AM
1506
SG
142 mg/dL
0.8 U
CARBS
0g
0.0 U
BOLUS
0.8 U
DETAILS
DELIVER BOLUS

FIG. 15

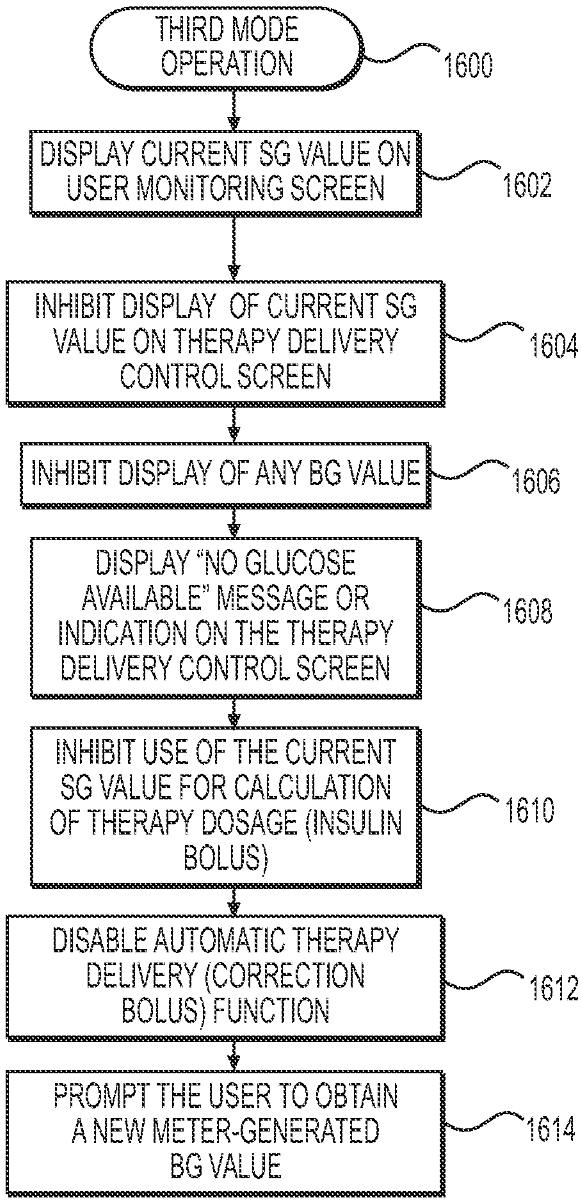
THIRD MODE OPERATION
1600
DISPLAY CURRENT SG VALUE ON USER MONITORING SCREEN
1602
INHIBIT DISPLAY OF CURRENT SG VALUE ON THERAPY DELIVERY CONTROL SCREEN
1604
INHIBIT DISPLAY OF ANY BG VALUE
1606
DISPLAY "NO GLUCOSE AVAILABLE" MESSAGE OR INDICATION ON THE THERAPY DELIVERY CONTROL SCREEN
1608
INHIBIT USE OF THE CURRENT SG VALUE FOR CALCULATION OF THERAPY DOSAGE (INSULIN BOLUS)
1610
DISABLE AUTOMATIC THERAPY DELIVERY (CORRECTION BOLUS) FUNCTION
1612
PROMPT THE USER TO OBTAIN A NEW METER-GENERATED BG VALUE
1614

FIG. 16

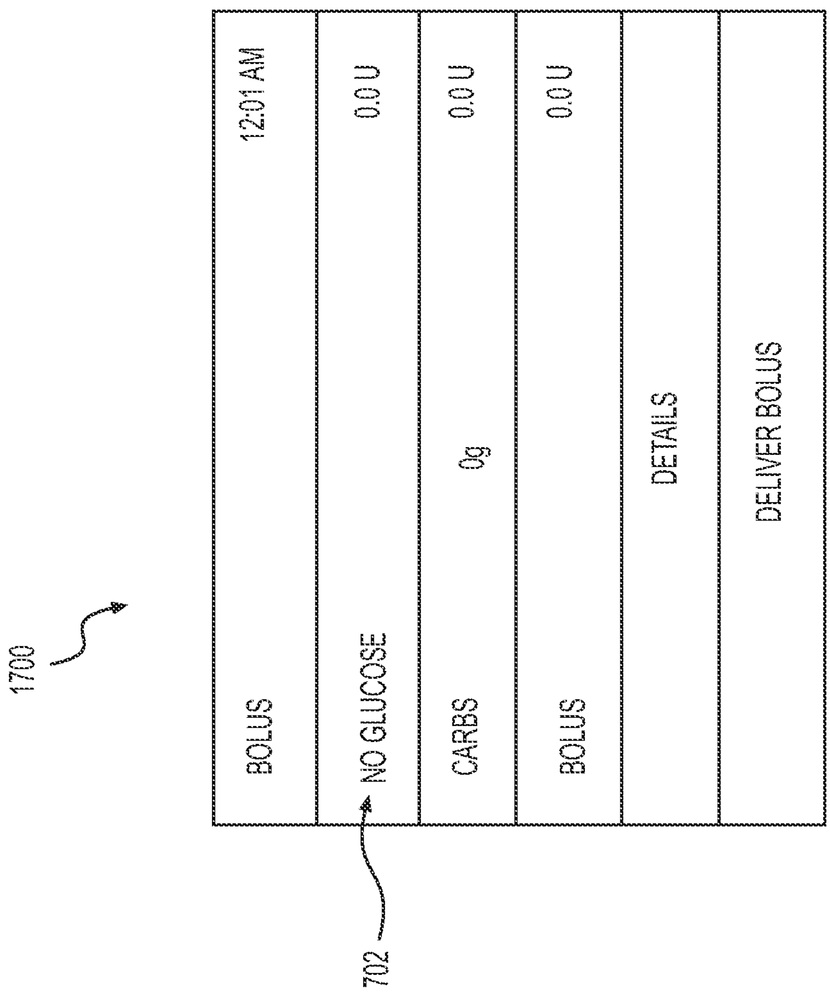
1700
BOLUS
12:01 AM
NO GLUCOSE
0.0 U
CARBS
0g
0.0 U
BOLUS
0.0 U
DETAILS
DELIVER BOLUS
1702

FIG. 17

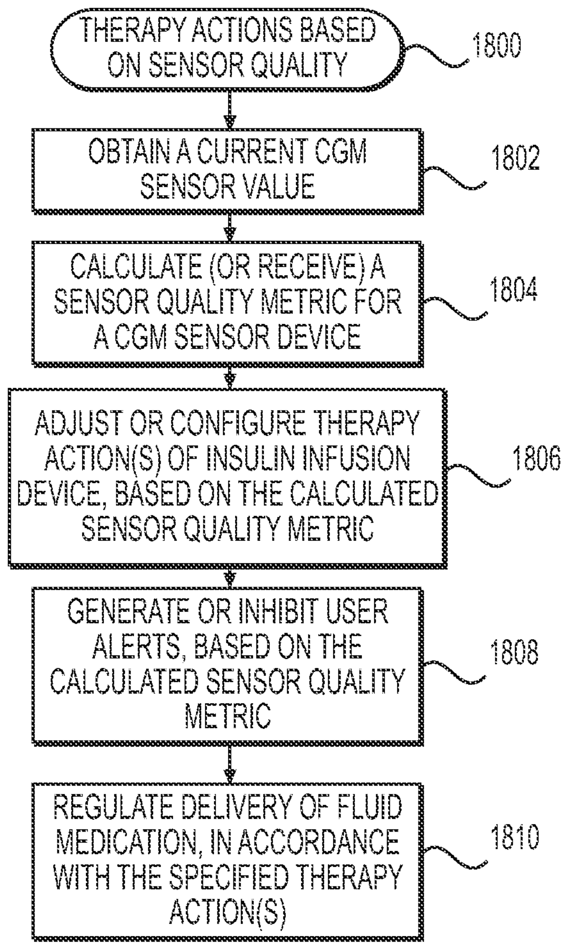
THERAPY ACTIONS BASED ON SENSOR QUALITY
1800
OBTAIN A CURRENT CGM SENSOR VALUE
1802
CALCULATE (OR RECEIVE) A SENSOR QUALITY METRIC FOR A CGM SENSOR DEVICE
1804
ADJUST OR CONFIGURE THERAPY ACTION(S) OF INSULIN INFUSION DEVICE, BASED ON THE CALCULATED SENSOR QUALITY METRIC
1806
GENERATE OR INHIBIT USER ALERTS, BASED ON THE CALCULATED SENSOR QUALITY METRIC
1808
REGULATE DELIVERY OF FLUID MEDICATION, IN ACCORDANCE WITH THE SPECIFIED THERAPY ACTION(S)
1810

FIG. 18

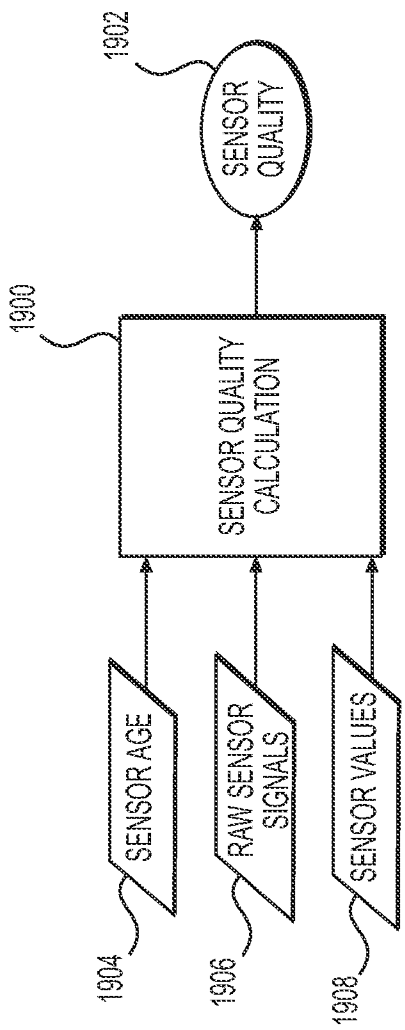
1902
SENSOR QUALITY
1900
SENSOR QUALITY CALCULATION
SENSOR AGE
RAW SENSOR SIGNALS
SENSOR VALUES
1904
1906
1908

FIG. 19

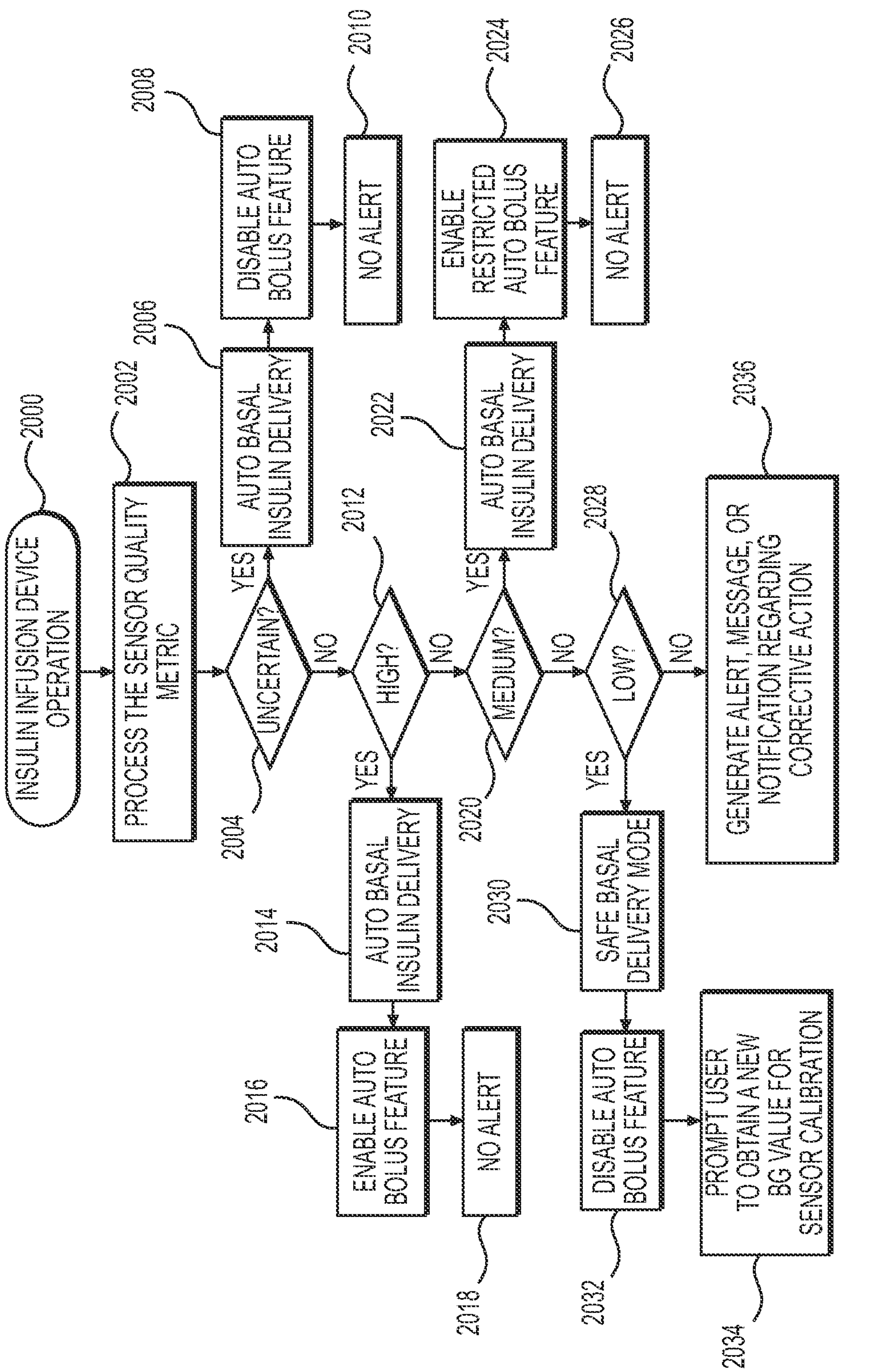
2000
INSULIN INFUSION DEVICE OPERATION
2002
PROCESS THE SENSOR QUALITY METRIC
2004
UNCERTAIN?
YES
NO
2006
AUTO BASAL INSULIN DELIVERY
2008
DISABLE AUTO BOLUS FEATURE
2010
NO ALERT
2012
HIGH?
YES
NO
2014
AUTO BASAL INSULIN DELIVERY
2016
ENABLE AUTO BOLUS FEATURE
2018
NO ALERT
2020
MEDIUM?
YES
NO
2022
AUTO BASAL INSULIN DELIVERY
2024
ENABLE RESTRICTED AUTO BOLUS FEATURE
2026
NO ALERT
2028
LOW?
YES
NO
2030
SAFE BASAL DELIVERY MODE
2032
DISABLE AUTO BOLUS FEATURE
2034
PROMPT USER TO OBTAIN A NEW BG VALUE FOR SENSOR CALIBRATION
2036
GENERATE ALERT, MESSAGE, OR NOTIFICATION REGARDING CORRECTIVE ACTION

FIG. 20

CONTINUOUS ANALYTE SENSOR QUALITY MEASURES AND RELATED THERAPY ACTIONS FOR AN AUTOMATED THERAPY DELIVERY SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 16/856,838, filed Apr. 23, 2020, the entire contents of which are herein incorporated by reference for all purposes.

TECHNICAL FIELD

Embodiments of the subject matter described herein relate generally to a system that delivers therapy (e.g., medicine) to a user. More specifically, the subject matter described herein relates to user interface and quality checking features of an insulin infusion system that obtains glucose readings from a continuous glucose sensor.

BACKGROUND

Medical therapy delivery systems, such as fluid infusion pump devices, are relatively well known in the medical arts, for use in delivering or dispensing an agent, such as insulin or another prescribed medication, to a patient. A typical infusion pump includes a pump drive system that usually includes a small motor and drive train components that convert rotational motor motion to a translational displacement of a plunger (or stopper) in a fluid reservoir, which delivers medication from the reservoir to the body of a patient via a fluid path created between the reservoir and the body of a patient. Use of infusion pump therapy has been increasing, especially for delivering insulin for diabetics.

Control schemes have been developed to allow insulin infusion pumps to monitor and regulate a patient's blood glucose level in a substantially continuous and autonomous manner. Managing a diabetic's blood glucose level is complicated by variations in a patient's daily activities (e.g., exercise, carbohydrate consumption, and the like) in addition to variations in the patient's individual insulin response and potentially other factors. Some control schemes may attempt to proactively account for daily activities to minimize glucose excursions. At the same time, patients may manually initiate delivery of insulin prior to or contemporaneously with consuming a meal (e.g., a meal bolus or correction bolus) to prevent spikes or swings in the patient's blood glucose level that could otherwise result from the impending consumption of carbohydrates and the response time of the control scheme.

BRIEF SUMMARY

Techniques disclosed herein relate to continuous analyte sensor quality measures. The techniques may be practiced with a processor-implemented method, a system comprising one or more processors and one or more processor-readable media, and/or one or more non-transitory processor-readable media.

In some embodiments, the techniques may involve obtaining a current sensor-generated value that is indicative of a physiological characteristic of a user of a medical device, the current sensor-generated value produced in response to operation of a continuous analyte sensor device. The techniques may further involve obtaining a sensor quality metric that indicates accuracy of the current sensor-generated value. The techniques may further involve causing, in response to obtaining the sensor quality metric, configuration of a quality-specific operating mode of the medical device, the quality-specific operating mode comprising separate regulation of basal and bolus deliveries of a fluid medication based on the obtained sensor quality metric. The techniques may further involve causing regulation of fluid medication delivery from the medical device, in accordance with the current sensor-generated value and the quality-specific operating mode of the medical device.

This summary is provided to introduce a selection of concepts in a simplified form that are further described below in the detailed description. This summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the subject matter may be derived by referring to the detailed description and claims when considered in conjunction with the following figures, wherein like reference numbers refer to similar elements throughout the figures.

FIG. **1** depicts an exemplary embodiment of an infusion system;

FIG. **2** depicts a plan view of an exemplary embodiment of a fluid infusion device suitable for use in the infusion system of FIG. **1**;

FIG. **3** is an exploded perspective view of the fluid infusion device of FIG. **2**;

FIG. **4** is a cross-sectional view of the fluid infusion device of FIGS. **2-3** as viewed along line **4-4** in FIG. **3** when assembled with a reservoir inserted in the infusion device;

FIG. **5** is a block diagram of an exemplary infusion system suitable for use with a fluid infusion device in one or more embodiments;

FIG. **6** is a block diagram of an exemplary pump control system suitable for use in the infusion device in the infusion system of FIG. **5** in one or more embodiments;

FIG. **7** is a block diagram of a closed-loop control system that may be implemented or otherwise supported by the pump control system in the fluid infusion device of FIGS. **5-6** in one or more exemplary embodiments;

FIG. **8** is a block diagram of an exemplary patient monitoring system;

FIG. **9** is a flow chart that illustrates an exemplary embodiment of a process for operating a medical device, such as an insulin infusion device;

FIG. **10** is a flow chart that illustrates operation of an insulin infusion device in a first mode;

FIG. **11** is a schematic representation of a user monitoring screen on an insulin infusion device, with a meter-generated blood glucose (BG) value displayed thereon;

FIG. **12** is a schematic representation of a therapy delivery control screen on an insulin infusion device, with a BG value displayed thereon;

FIG. **13** is a flow chart that illustrates operation of an insulin infusion device in a second mode;

FIG. **14** is a schematic representation of a user monitoring screen on an insulin infusion device, with a sensor-generated glucose (SG) value displayed thereon;

FIG. **15** is a schematic representation of a therapy delivery control screen on an insulin infusion device, with an SG value displayed thereon;

FIG. **16** is a flow chart that illustrates operation of an insulin infusion device in a third mode;

FIG. **17** is a schematic representation of a therapy delivery control screen on an insulin infusion device, with neither a BG value nor an SG value displayed thereon;

FIG. **18** is a flow chart that illustrates an exemplary embodiment of a method of controlling operation of a medical device to regulate therapy actions based on sensor quality;

FIG. **19** is a block diagram that illustrates the generation of a sensor quality metric in accordance with an exemplary embodiment; and

FIG. **20** is a flow chart that illustrates operation of an insulin infusion device in accordance with an exemplary embodiment.

DETAILED DESCRIPTION

The following detailed description is merely illustrative in nature and is not intended to limit the embodiments of the subject matter or the application and uses of such embodiments. As used herein, the word "exemplary" means "serving as an example, instance, or illustration." Any implementation described herein as exemplary is not necessarily to be construed as preferred or advantageous over other implementations. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

Exemplary embodiments of the subject matter described herein are implemented in conjunction with medical devices, such as portable electronic medical devices. Although many different applications are possible, the following description focuses on embodiments that incorporate an insulin infusion device (or insulin pump) as part of an infusion system deployment. For the sake of brevity, conventional techniques related to infusion system operation, insulin pump and/or infusion set operation, and other functional aspects of the systems (and the individual operating components of the systems) may not be described in detail here. Examples of infusion pumps may be of the type described in, but not limited to, U.S. Pat. Nos. 4,562,751; 4,685,903; 5,080,653; 5,505,709; 5,097,122; 6,485,465; 6,554,798; 6,558,320; 6,558,351; 6,641,533; 6,659,980; 6,752,787; 6,817,990; 6,932,584; and 7,621,893; each of which are herein incorporated by reference.

Generally, a fluid infusion device includes a motor or other actuation arrangement that is operable to linearly displace a plunger (or stopper) of a fluid reservoir provided within the fluid infusion device to deliver a dosage of fluid medication, such as insulin, to the body of a user. Dosage commands that govern operation of the motor may be generated in an automated manner in accordance with the delivery control scheme associated with a particular operating mode, and the dosage commands may be generated in a manner that is influenced by a current (or most recent) measurement of a physiological condition in the body of the user. For example, in a closed-loop or automatic operating mode, dosage commands may be generated based on a difference between a current (or most recent) measurement of the interstitial fluid glucose level in the body of the user and a target (or reference) glucose setpoint value. In this regard, the rate of infusion may vary as the difference between a current measurement value and the target measurement value fluctuates. For purposes of explanation, the subject matter is described herein in the context of the infused fluid being insulin for regulating a glucose level of a user (or patient); however, it should be appreciated that many other fluids may be administered through infusion, and the subject matter described herein is not necessarily limited to use with insulin.

An insulin infusion pump can be operated in an automatic mode wherein basal insulin is delivered at a rate that is automatically adjusted for the user. While controlling the delivery of basal insulin in this manner, the pump can also control the delivery of correction boluses to account for rising glucose trends due to meals, stress, hormonal fluctuations, etc. Ideally, the amount of a correction bolus should be accurately calculated and administered to maintain the user's blood glucose within the desired range. In particular, an automatically generated and delivered correction bolus should safely manage the user's blood glucose level and keep it above a defined hypoglycemic threshold level.

Turning now to FIG. **1**, one exemplary embodiment of an infusion system **100** includes, without limitation, a fluid infusion device (or infusion pump) **102**, a sensing arrangement **104**, a command control device (CCD) **106**, and a computer **108**. The components of an infusion system **100** may be realized using different platforms, designs, and configurations, and the embodiment shown in FIG. **1** is not exhaustive or limiting. In some embodiments, the infusion device **102** and the sensing arrangement **104** are secured at desired locations on the body of a user (or patient), as illustrated in FIG. **1**. In this regard, the locations at which the infusion device **102** and the sensing arrangement **104** are secured to the body of the user in FIG. **1** are provided only as a representative, non-limiting, example. The elements of the infusion system **100** may be similar to those described in U.S. Pat. No. 8,674,288, the subject matter of which is hereby incorporated by reference in its entirety.

In the illustrated embodiment of FIG. **1**, the infusion device **102** is designed as a portable medical device suitable for infusing a fluid, a liquid, a gel, or other medicament into the body of a user. In exemplary embodiments, the infused fluid is insulin, although many other fluids may be administered through infusion such as, but not limited to, HIV drugs, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like. In some embodiments, the fluid may include a nutritional supplement, a dye, a tracing medium, a saline medium, a hydration medium, or the like.

The sensing arrangement **104** generally represents the components of the infusion system **100** configured to sense, detect, measure or otherwise quantify a condition of the user, and may include a sensor, a monitor, or the like, for providing data indicative of the condition that is sensed, detected, measured or otherwise monitored by the sensing arrangement. In this regard, the sensing arrangement **104** may include electronics and enzymes reactive to a biological condition, such as a blood glucose level, or the like, of the user, and provide data indicative of the blood glucose level to the infusion device **102**, the CCD **106** and/or the computer **108**. For example, the infusion device **102**, the CCD **106** and/or the computer **108** may include a display for presenting information or data to the user based on the sensor data received from the sensing arrangement **104**, such as, for example, a current glucose level of the user, a graph or chart of the user's glucose level versus time, device status indicators, alert messages, or the like. In other embodiments, the infusion device **102**, the CCD **106** and/or the computer **108** may include electronics and software that are configured to analyze sensor data and operate the infusion device **102** to deliver fluid to the body of the user based on the sensor data and/or preprogrammed delivery routines. Thus, in exemplary embodiments, one or more of the infusion device **102**, the sensing arrangement **104**, the CCD **106**, and/or the computer **108** includes a transmitter, a receiver, and/or other transceiver electronics that allow for communication with other components of the infusion system **100**, so that the sensing arrangement **104** may transmit sensor data or monitor data to one or more of the infusion device **102**, the CCD **106** and/or the computer **108**.

Still referring to FIG. **1**, in various embodiments, the sensing arrangement **104** may be secured to the body of the user or embedded in the body of the user at a location that is remote from the location at which the infusion device **102** is secured to the body of the user. In various other embodiments, the sensing arrangement **104** may be incorporated within the infusion device **102**. In other embodiments, the sensing arrangement **104** may be separate and apart from the infusion device **102**, and may be, for example, part of the CCD **106**. In such embodiments, the sensing arrangement **104** may be configured to receive a biological sample, analyte, or the like, to measure a condition of the user.

In some embodiments, the CCD **106** and/or the computer **108** may include electronics and other components configured to perform processing, delivery routine storage, and to control the infusion device **102** in a manner that is influenced by sensor data measured by and/or received from the sensing arrangement **104**. By including control functions in the CCD **106** and/or the computer **108**, the infusion device **102** may be made with more simplified electronics. However, in other embodiments, the infusion device **102** may include all control functions, and may operate without the CCD **106** and/or the computer **108**. In various embodiments, the CCD **106** may be a portable electronic device. In addition, in various embodiments, the infusion device **102** and/or the sensing arrangement **104** may be configured to transmit data to the CCD **106** and/or the computer **108** for display or processing of the data by the CCD **106** and/or the computer **108**.

In some embodiments, the CCD **106** and/or the computer **108** may provide information to the user that facilitates the user's subsequent use of the infusion device **102**. For example, the CCD **106** may provide information to the user to allow the user to determine the rate or dose of medication to be administered into the user's body. In other embodiments, the CCD **106** may provide information to the infusion device **102** to autonomously control the rate or dose of medication administered into the body of the user. In some embodiments, the sensing arrangement **104** may be integrated into the CCD **106**. Such embodiments may allow the user to monitor a condition by providing, for example, a sample of his or her blood to the sensing arrangement **104** to assess his or her condition. In some embodiments, the sensing arrangement **104** and the CCD **106** may be used for determining glucose levels in the blood and/or body fluids of the user without the use of, or necessity of, a wire or cable connection between the infusion device **102** and the sensing arrangement **104** and/or the CCD **106**.

In some embodiments, the sensing arrangement **104** and/or the infusion device **102** are cooperatively configured to utilize a closed-loop system for delivering fluid to the user. Examples of sensing devices and/or infusion pumps utilizing closed-loop systems may be found at, but are not limited to, the following U.S. Pat. Nos. 6,088,608, 6,119,028, 6,589,229, 6,740,072, 6,827,702, 7,323,142, and 7,402,153 or United States Patent Application Publication No. 2014/0066889, all of which are incorporated herein by reference in their entirety. In such embodiments, the sensing arrangement **104** is configured to sense or measure a condition of the user, such as, blood glucose level or the like. The infusion device **102** is configured to deliver fluid in response to the condition sensed by the sensing arrangement **104**. In turn, the sensing arrangement **104** continues to sense or otherwise quantify a current condition of the user, thereby allowing the infusion device **102** to deliver fluid continuously in response to the condition currently (or most recently) sensed by the sensing arrangement **104** indefinitely. In some embodiments, the sensing arrangement **104** and/or the infusion device **102** may be configured to utilize the closed-loop system only for a portion of the day, for example only when the user is asleep or awake.

FIGS. **2-4** depict one exemplary embodiment of a fluid infusion device **200** (or alternatively, infusion pump) suitable for use in an infusion system, such as, for example, as infusion device **102** in the infusion system **100** of FIG. **1**. The fluid infusion device **200** is a portable medical device designed to be carried or worn by a patient (or user), and the fluid infusion device **200** may leverage any number of conventional features, components, elements, and characteristics of existing fluid infusion devices, such as, for example, some of the features, components, elements, and/or characteristics described in U.S. Pat. Nos. 6,485,465 and 7,621,893. It should be appreciated that FIGS. **2-4** depict some aspects of the infusion device **200** in a simplified manner; in some embodiments, the infusion device **200** could include additional elements, features, or components that are not shown or described in detail herein.

As best illustrated in FIGS. **2-3**, the illustrated embodiment of the fluid infusion device **200** includes a housing **202** adapted to receive a fluid-containing reservoir **205**. An opening **220** in the housing **202** accommodates a fitting **223** (or cap) for the reservoir **205**, with the fitting **223** being configured to mate or otherwise interface with tubing **221** of an infusion set **225** that provides a fluid path to/from the body of the user. In this manner, fluid communication from the interior of the reservoir **205** to the user is established via the tubing **221**. The illustrated fluid infusion device **200** includes a human-machine interface (HMI) **230** (or user interface) that includes elements **232**, **234** that can be manipulated by the user to administer a bolus of fluid (e.g., insulin), to change therapy settings, to change user preferences, to select display features, and the like. The infusion device also includes a display device **226**, such as a liquid crystal display (LCD) or another suitable display device, that can be used to present various types of information or data to the user, such as, without limitation: the current glucose level of the patient; the time; a graph or chart of the patient's glucose level versus time; device status indicators; etc.

The housing **202** is formed from a substantially rigid material having a hollow interior **214** adapted to allow an electronics assembly **204**, a sliding member (or slide) **206**, a drive system **208**, a sensor assembly **210**, and a drive system capping member **212** to be disposed therein in addition to the reservoir **205**, with the contents of the housing **202** being enclosed by a housing capping member **216**. The opening **220**, the slide **206**, and the drive system **208** are coaxially aligned in an axial direction (indicated by arrow **218**), whereby the drive system **208** facilitates linear displacement of the slide **206** in the axial direction **218** to dispense fluid from the reservoir **205** (after the reservoir **205** has been inserted into opening **220**), with the sensor assembly **210** being configured to measure axial forces (e.g., forces aligned with the axial direction **218**) exerted on the sensor assembly **210** responsive to operating the drive system **208** to displace the slide **206**. In various embodiments, the sensor assembly **210** may be utilized to detect one or more of the following: an occlusion in a fluid path that slows, prevents, or otherwise degrades fluid delivery from the reservoir **205** to a user's body; when the reservoir **205** is empty; when the slide **206** is properly seated with the reservoir **205**; when a fluid dose has been delivered; when the infusion device **200** is subjected to shock or vibration; when the infusion device **200** requires maintenance.

Depending on the embodiment, the fluid-containing reservoir **205** may be realized as a syringe, a vial, a cartridge, a bag, or the like. In certain embodiments, the infused fluid is insulin, although many other fluids may be administered through infusion such as, but not limited to, HIV drugs, drugs to treat pulmonary hypertension, iron chelation drugs, pain medications, anti-cancer treatments, medications, vitamins, hormones, or the like. As best illustrated in FIGS. **3-4**, the reservoir **205** typically includes a reservoir barrel **219** that contains the fluid and is concentrically and/or coaxially aligned with the slide **206** (e.g., in the axial direction **218**) when the reservoir **205** is inserted into the infusion device **200**. The end of the reservoir **205** proximate the opening **220** may include or otherwise mate with the fitting **223**, which secures the reservoir **205** in the housing **202** and prevents displacement of the reservoir **205** in the axial direction **218** with respect to the housing **202** after the reservoir **205** is inserted into the housing **202**. As described above, the fitting **223** extends from (or through) the opening **220** of the housing **202** and mates with tubing **221** to establish fluid communication from the interior of the reservoir **205** (e.g., reservoir barrel **219**) to the user via the tubing **221** and infusion set **225**. The opposing end of the reservoir **205** proximate the slide **206** includes a plunger **217** (or stopper) positioned to push fluid from inside the barrel **219** of the reservoir **205** along a fluid path through tubing **221** to a user. The slide **206** is configured to mechanically couple or otherwise engage with the plunger **217**, thereby becoming seated with the plunger **217** and/or reservoir **205**. Fluid is forced from the reservoir **205** via tubing **221** as the drive system **208** is operated to displace the slide **206** in the axial direction **218** toward the opening **220** in the housing **202**.

In the illustrated embodiment of FIGS. **3-4**, the drive system **208** includes a motor assembly **207** and a drive screw **209**. The motor assembly **207** includes a motor that is coupled to drive train components of the drive system **208** that are configured to convert rotational motor motion to a translational displacement of the slide **206** in the axial direction **218**, and thereby engaging and displacing the plunger **217** of the reservoir **205** in the axial direction **218**. In some embodiments, the motor assembly **207** may also be powered to translate the slide **206** in the opposing direction (e.g., the direction opposite direction **218**) to retract and/or detach from the reservoir **205** to allow the reservoir **205** to be replaced. In exemplary embodiments, the motor assembly **207** includes a brushless DC (BLDC) motor having one or more permanent magnets mounted, affixed, or otherwise disposed on its rotor. However, the subject matter described herein is not necessarily limited to use with BLDC motors, and in alternative embodiments, the motor may be realized as a solenoid motor, an AC motor, a stepper motor, a piezoelectric caterpillar drive, a shape memory actuator drive, an electrochemical gas cell, a thermally driven gas cell, a bimetallic actuator, or the like. The drive train components may comprise one or more lead screws, cams, ratchets, jacks, pulleys, pawls, clamps, gears, nuts, slides, bearings, levers, beams, stoppers, plungers, sliders, brackets, guides, bearings, supports, bellows, caps, diaphragms, bags, heaters, or the like. In this regard, although the illustrated embodiment of the infusion pump utilizes a coaxially aligned drive train, the motor could be arranged in an offset or otherwise non-coaxial manner, relative to the longitudinal axis of the reservoir **205**.

As best shown in FIG. **4**, the drive screw **209** mates with threads **402** internal to the slide **206**. When the motor assembly **207** is powered and operated, the drive screw **209** rotates, and the slide **206** is forced to translate in the axial direction **218**. In an exemplary embodiment, the infusion device **200** includes a sleeve **211** to prevent the slide **206** from rotating when the drive screw **209** of the drive system **208** rotates. Thus, rotation of the drive screw **209** causes the slide **206** to extend or retract relative to the drive motor assembly **207**. When the fluid infusion device is assembled and operational, the slide **206** contacts the plunger **217** to engage the reservoir **205** and control delivery of fluid from the infusion device **200**. In an exemplary embodiment, the shoulder portion **215** of the slide **206** contacts or otherwise engages the plunger **217** to displace the plunger **217** in the axial direction **218**. In alternative embodiments, the slide **206** may include a threaded tip **213** capable of being detachably engaged with internal threads **404** on the plunger **217** of the reservoir **205**, as described in detail in U.S. Pat. Nos. 6,248,093 and 6,485,465, which are incorporated by reference herein.

As illustrated in FIG. **3**, the electronics assembly **204** includes control electronics **224** coupled to the display device **226**, with the housing **202** including a transparent window portion **228** that is aligned with the display device **226** to allow the display device **226** to be viewed by the user when the electronics assembly **204** is disposed within the interior **214** of the housing **202**. The control electronics **224** generally represent the hardware, firmware, processing logic and/or software (or combinations thereof) configured to control operation of the motor assembly **207** and/or drive system **208**, as described in greater detail below in the context of FIG. **5**. The control electronics **224** is also suitably configured and designed to support various user interface, input/output, and display features of the fluid infusion device **200**. Whether such functionality is implemented as hardware, firmware, a state machine, or software depends upon the particular application and design constraints imposed on the embodiment. Those familiar with the concepts described here may implement such functionality in a suitable manner for each particular application, but such implementation decisions should not be interpreted as being restrictive or limiting. In an exemplary embodiment, the control electronics **224** includes one or more programmable controllers that may be programmed to control operation of the infusion device **200**.

The motor assembly **207** includes one or more electrical leads **236** adapted to be electrically coupled to the electronics assembly **204** to establish communication between the control electronics **224** and the motor assembly **207**. In response to command signals from the control electronics **224** that operate a motor driver (e.g., a power converter) to regulate the amount of power supplied to the motor from a power supply, the motor actuates the drive train components of the drive system **208** to displace the slide **206** in the axial direction **218** to force fluid from the reservoir **205** along a fluid path (including tubing **221** and an infusion set), thereby administering doses of the fluid contained in the reservoir **205** into the user's body. Preferably, the power supply is realized one or more batteries contained within the housing **202**. Alternatively, the power supply may be a solar panel, capacitor, AC or DC power supplied through a power cord, or the like. In some embodiments, the control electronics **224** may operate the motor of the motor assembly **207** and/or drive system **208** in a stepwise manner, typically on an intermittent basis; to administer discrete precise doses of the fluid to the user according to programmed delivery profiles.

Referring to FIGS. **2-4**, as described above, the user interface **230** includes HMI elements, such as buttons **232** and a directional pad **234**, that are formed on a graphic keypad overlay **231** that overlies a keypad assembly **233**, which includes features corresponding to the buttons **232**, directional pad **234** or other user interface items indicated by the graphic keypad overlay **231**. When assembled, the keypad assembly **233** is coupled to the control electronics **224**, thereby allowing the HMI elements **232**, **234** to be manipulated by the user to interact with the control electronics **224** and control operation of the infusion device **200**, for example, to administer a bolus of insulin, to change therapy settings, to change user preferences, to select display features, to set or disable alarms and reminders, and the like. In this regard, the control electronics **224** maintains and/or provides information to the display device **226** regarding program parameters, delivery profiles, pump operation, alarms, warnings, statuses, or the like, which may be adjusted using the HMI elements **232**, **234**. In various embodiments, the HMI elements **232**, **234** may be realized as physical objects (e.g., buttons, knobs, joysticks, and the like) or virtual objects (e.g., graphical user interface elements that use touch-sensing and/or proximity-sensing technologies). For example, in some embodiments, the display device **226** may be realized as a touch screen or touch-sensitive display, and in such embodiments, the features and/or functionality of the HMI elements **232**, **234** may be integrated into the display device **226** and the HMI **230** may not be present. In some embodiments, the electronics assembly **204** may also include alert generating elements coupled to the control electronics **224** and suitably configured to generate one or more types of feedback, such as, without limitation: audible feedback; visual feedback; haptic (physical) feedback; or the like.

Referring to FIGS. **3-4**, in accordance with one or more embodiments, the sensor assembly **210** includes a back plate structure **250** and a loading element **260**. The loading element **260** is disposed between the capping member **212** and a beam structure **270** that includes one or more beams having sensing elements disposed thereon that are influenced by compressive force applied to the sensor assembly **210** that deflects the one or more beams, as described in greater detail in U.S. Pat. No. 8,474,332, which is incorporated by reference herein. In exemplary embodiments, the back plate structure **250** is affixed, adhered, mounted, or otherwise mechanically coupled to the bottom surface **238** of the drive system **208** such that the back plate structure **250** resides between the bottom surface **238** of the drive system **208** and the housing capping member **216**. The drive system capping member **212** is contoured to accommodate and conform to the bottom of the sensor assembly **210** and the drive system **208**. The drive system capping member **212** may be affixed to the interior of the housing **202** to prevent displacement of the sensor assembly **210** in the direction opposite the direction of force provided by the drive system **208** (e.g., the direction opposite direction **218**). Thus, the sensor assembly **210** is positioned between the motor assembly **207** and secured by the capping member **212**, which prevents displacement of the sensor assembly **210** in a downward direction opposite the direction of the arrow that represents the axial direction **218**, such that the sensor assembly **210** is subjected to a reactionary compressive force when the drive system **208** and/or motor assembly **207** is operated to displace the slide **206** in the axial direction **218** in opposition to the fluid pressure in the reservoir **205**. Under normal operating conditions, the compressive force applied to the sensor assembly **210** is correlated with the fluid pressure in the reservoir **205**. As shown, electrical leads **240** are adapted to electrically couple the sensing elements of the sensor assembly **210** to the electronics assembly **204** to establish communication to the control electronics **224**, wherein the control electronics **224** are configured to measure, receive, or otherwise obtain electrical signals from the sensing elements of the sensor assembly **210** that are indicative of the force applied by the drive system **208** in the axial direction **218**.

FIG. **5** depicts an exemplary embodiment of an infusion system **500** suitable for use with an infusion device **502**, such as any one of the infusion devices **102**, **200** described above. The infusion system **500** is capable of controlling or otherwise regulating a physiological condition in the body **501** of a patient to a desired (or target) value or otherwise maintain the condition within a range of acceptable values in an automated or autonomous manner. In one or more exemplary embodiments, the condition being regulated is sensed, detected, measured or otherwise quantified by a sensing arrangement **504** (e.g., a blood glucose sensing arrangement **504**) communicatively coupled to the infusion device **502**. However, it should be noted that in alternative embodiments, the condition being regulated by the infusion system **500** may be correlative to the measured values obtained by the sensing arrangement **504**. That said, for clarity and purposes of explanation, the subject matter may be described herein in the context of the sensing arrangement **504** being realized as a glucose sensing arrangement that senses, detects, measures or otherwise quantifies the patient's glucose level, which is being regulated in the body **501** of the patient by the infusion system **500**.

In exemplary embodiments, the sensing arrangement **504** includes one or more interstitial glucose sensing elements that generate or otherwise output electrical signals (alternatively referred to herein as measurement signals) having a signal characteristic that is correlative to, influenced by, or otherwise indicative of the relative interstitial fluid glucose level in the body **501** of the patient. The output electrical signals are filtered or otherwise processed to obtain a measurement value indicative of the patient's interstitial fluid glucose level. In exemplary embodiments, a blood glucose meter **530**, such as a finger stick device, is utilized to directly sense, detect, measure or otherwise quantify the blood glucose in the body **501** of the patient. In this regard, the blood glucose meter **530** outputs or otherwise provides a measured blood glucose value that may be utilized as a reference measurement for calibrating the sensing arrangement **504** and converting a measurement value indicative of the patient's interstitial fluid glucose level into a corresponding calibrated blood glucose value. For purposes of explanation, the calibrated blood glucose value calculated based on the electrical signals output by the sensing element(s) of the sensing arrangement **504** may alternatively be referred to herein as the sensor glucose value, the sensed glucose value, or variants thereof.

In exemplary embodiments, the infusion system **500** also includes one or more additional sensing arrangements **506**, **508** configured to sense, detect, measure or otherwise quantify a characteristic of the body **501** of the patient that is indicative of a condition in the body **501** of the patient. In this regard, in addition to the glucose sensing arrangement **504**, one or more auxiliary sensing arrangements **506** may be worn, carried, or otherwise associated with the body **501** of the patient to measure characteristics or conditions of the patient (or the patient's activity) that may influence the patient's glucose levels or insulin sensitivity. For example, a heart rate sensing arrangement **506** could be worn on or otherwise associated with the patient's body **501** to sense, detect, measure or otherwise quantify the patient's heart rate, which, in turn, may be indicative of exercise (and the intensity thereof) that is likely to influence the patient's glucose levels or insulin response in the body **501**. In yet another embodiment, another invasive, interstitial, or subcutaneous sensing arrangement **506** may be inserted into the body **501** of the patient to obtain measurements of another physiological condition that may be indicative of exercise (and the intensity thereof), such as, for example, a lactate sensor, a ketone sensor, or the like. Depending on the embodiment, the auxiliary sensing arrangement(s) **506** could be realized as a standalone component worn by the patient, or alternatively, the auxiliary sensing arrangement(s) **506** may be integrated with the infusion device **502** or the glucose sensing arrangement **504**.

The illustrated infusion system **500** also includes an acceleration sensing arrangement **508** (or accelerometer) that may be worn on or otherwise associated with the patient's body **501** to sense, detect, measure or otherwise quantify an acceleration of the patient's body **501**, which, in turn, may be indicative of exercise or some other condition in the body **501** that is likely to influence the patient's insulin response. While the acceleration sensing arrangement **508** is depicted as being integrated into the infusion device **502** in FIG. **5**, in alternative embodiments, the acceleration sensing arrangement **508** may be integrated with another sensing arrangement **504**, **506** on the body **501** of the patient, or the acceleration sensing arrangement **508** may be realized as a separate standalone component that is worn by the patient.

In the illustrated embodiment, the pump control system **520** generally represents the electronics and other components of the infusion device **502** that control operation of the fluid infusion device **502** according to a desired infusion delivery program in a manner that is influenced by the sensed glucose value indicating the current glucose level in the body **501** of the patient. For example, to support a closed-loop operating mode, the pump control system **520** maintains, receives, or otherwise obtains a target or commanded glucose value, and automatically generates or otherwise determines dosage commands for operating an actuation arrangement, such as a motor **532**, to displace the plunger **517** and deliver insulin to the body **501** of the patient based on the difference between the sensed glucose value and the target glucose value. In other operating modes, the pump control system **520** may generate or otherwise determine dosage commands configured to maintain the sensed glucose value below an upper glucose limit, above a lower glucose limit, or otherwise within a desired range of glucose values. In some embodiments, the infusion device **502** may store or otherwise maintain the target value, upper and/or lower glucose limit(s), insulin delivery limit(s), and/or other glucose threshold value(s) in a data storage element accessible to the pump control system **520**. As described in greater detail, in one or more exemplary embodiments, the pump control system **520** automatically adjusts or adapts one or more parameters or other control information used to generate commands for operating the motor **532** in a manner that accounts for a likely change in the patient's glucose level or insulin response resulting from a meal, exercise, or other activity.

Still referring to FIG. **5**, the target glucose value and other threshold glucose values utilized by the pump control system **520** may be received from an external component (e.g., CCD **106** and/or computing device **108**) or be input by a patient via a user interface element **540** associated with the infusion device **502**. In some embodiments, the one or more user interface element(s) **540** associated with the infusion device **502** typically include at least one input user interface element, such as, for example, a button, a keypad, a keyboard, a knob, a joystick, a mouse, a touch panel, a touchscreen, a microphone or another audio input device, and/or the like. Additionally, the one or more user interface element(s) **540** include at least one output user interface element, such as, for example, a display device (e.g., a light-emitting diode or the like), a display device (e.g., a liquid crystal display or the like), a speaker or another audio output device, a haptic feedback device, or the like, for providing notifications or other information to the patient. It should be noted that although FIG. **5** depicts the user interface element(s) **540** as being separate from the infusion device **502**, in some embodiments, one or more of the user interface element(s) **540** may be integrated with the infusion device **502**. Furthermore, in some embodiments, one or more user interface element(s) **540** are integrated with the sensing arrangement **504** in addition to and/or in alternative to the user interface element(s) **540** integrated with the infusion device **502**. The user interface element(s) **540** may be manipulated by the patient to operate the infusion device **502** to deliver correction boluses, adjust target and/or threshold values, modify the delivery control scheme or operating mode, and the like, as desired.

Still referring to FIG. **5**, in the illustrated embodiment, the infusion device **502** includes a motor control module **512** coupled to a motor **532** (e.g., motor assembly **207**) that is operable to displace a plunger **517** (e.g., plunger **217**) in a reservoir (e.g., reservoir **205**) and provide a desired amount of fluid to the body **501** of a patient. In this regard, displacement of the plunger **517** results in the delivery of a fluid, such as insulin, that is capable of influencing the patient's physiological condition to the body **501** of the patient via a fluid delivery path (e.g., via tubing **221** of an infusion set **225**). A motor driver module **514** is coupled between an energy source **518** and the motor **532**. The motor control module **512** is coupled to the motor driver module **514**, and the motor control module **512** generates or otherwise provides command signals that operate the motor driver module **514** to provide current (or power) from the energy source **518** to the motor **532** to displace the plunger **517** in response to receiving, from a pump control system **520**, a dosage command indicative of the desired amount of fluid to be delivered.

In exemplary embodiments, the energy source **518** is realized as a battery housed within the infusion device **502** (e.g., within housing **202**) that provides direct current (DC) power. In this regard, the motor driver module **514** generally represents the combination of circuitry, hardware and/or other electrical components configured to convert or otherwise transfer DC power provided by the energy source **518** into alternating electrical signals applied to respective phases of the stator windings of the motor **532** that result in current flowing through the stator windings that generates a stator magnetic field and causes the rotor of the motor **532** to rotate. The motor control module **512** is configured to receive or otherwise obtain a commanded dosage from the pump control system **520**, convert the commanded dosage to a commanded translational displacement of the plunger **517**, and command, signal, or otherwise operate the motor driver module **514** to cause the rotor of the motor **532** to rotate by an amount that produces the commanded translational displacement of the plunger **517**. For example, the motor control module **512** may determine an amount of rotation of the rotor required to produce translational displacement of the plunger **517** that achieves the commanded dosage received from the pump control system **520**. Based on the current rotational position (or orientation) of the rotor with respect to the stator that is indicated by the output of the rotor sensing arrangement **516**, the motor control module **512** determines the appropriate sequence of alternating electrical signals to be applied to the respective phases of the stator windings that should rotate the rotor by the determined amount of rotation from its current position (or orientation). In embodiments where the motor **532** is realized as a BLDC motor, the alternating electrical signals commutate the respective phases of the stator windings at the appropriate orientation of the rotor magnetic poles with respect to the stator and in the appropriate order to provide a rotating stator magnetic field that rotates the rotor in the desired direction. Thereafter, the motor control module **512** operates the motor driver module **514** to apply the determined alternating electrical signals (e.g., the command signals) to the stator windings of the motor **532** to achieve the desired delivery of fluid to the patient.

When the motor control module **512** is operating the motor driver module **514**, current flows from the energy source **518** through the stator windings of the motor **532** to produce a stator magnetic field that interacts with the rotor magnetic field. In some embodiments, after the motor control module **512** operates the motor driver module **514** and/or motor **532** to achieve the commanded dosage, the motor control module **512** ceases operating the motor driver module **514** and/or motor **532** until a subsequent dosage command is received. In this regard, the motor driver module **514** and the motor **532** enter an idle state during which the motor driver module **514** effectively disconnects or isolates the stator windings of the motor **532** from the energy source **518**. In other words, current does not flow from the energy source **518** through the stator windings of the motor **532** when the motor **532** is idle, and thus, the motor **532** does not consume power from the energy source **518** in the idle state, thereby improving efficiency.

Depending on the embodiment, the motor control module **512** may be implemented or realized with a general purpose processor, a microprocessor, a controller, a microcontroller, a state machine, a content addressable memory, an application specific integrated circuit, a field programmable gate array, any suitable programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof, designed to perform the functions described herein. In exemplary embodiments, the motor control module **512** includes or otherwise accesses a data storage element or memory, including any sort of random access memory (RAM), read only memory (ROM), flash memory, registers, hard disks, removable disks, magnetic or optical mass storage, or any other short or long term storage media or other non-transitory computer-readable medium, which is capable of storing programming instructions for execution by the motor control module **512**. The computer-executable programming instructions, when read and executed by the motor control module **512**, cause the motor control module **512** to perform or otherwise support the tasks, operations, functions, and processes described herein.

It should be appreciated that FIG. **5** is a simplified representation of the infusion device **502** for purposes of explanation and is not intended to limit the subject matter described herein in any way. In this regard, depending on the embodiment, some features and/or functionality of the sensing arrangement **504** may implemented by or otherwise integrated into the pump control system **520**, or vice versa. Similarly, in some embodiments, the features and/or functionality of the motor control module **512** may implemented by or otherwise integrated into the pump control system **520**, or vice versa. Furthermore, the features and/or functionality of the pump control system **520** may be implemented by control electronics **224** located in the fluid infusion device **502**, while in alternative embodiments, the pump control system **520** may be implemented by a remote computing device that is physically distinct and/or separate from the infusion device **502**, such as, for example, the CCD **106** or the computing device **108**.

FIG. **6** depicts an exemplary embodiment of a pump control system **600** suitable for use as the pump control system **520** in FIG. **5** in accordance with one or more embodiments. The illustrated pump control system **600** includes, without limitation, a pump control module **602**, a communications interface **604**, and a data storage element (or memory) **606**. The pump control module **602** is coupled to the communications interface **604** and the memory **606**, and the pump control module **602** is suitably configured to support the operations, tasks, and/or processes described herein. In various embodiments, the pump control module **602** is also coupled to one or more user interface elements (e.g., user interface **230**, **540**) for receiving user inputs (e.g., target glucose values or other glucose thresholds) and providing notifications, alerts, or other therapy information to the patient.

The communications interface **604** generally represents the hardware, circuitry, logic, firmware and/or other components of the pump control system **600** that are coupled to the pump control module **602** and configured to support communications between the pump control system **600** and the various sensing arrangements **504**, **506**, **508**. In this regard, the communications interface **604** may include or otherwise be coupled to one or more transceiver modules capable of supporting wireless communications between the pump control system **520**, **600** and the sensing arrangement **504**, **506**, **508**. For example, the communications interface **604** may be utilized to receive sensor measurement values or other measurement data from each sensing arrangement **504**, **506**, **508** in an infusion system **500**. In other embodiments, the communications interface **604** may be configured to support wired communications to/from the sensing arrangement(s) **504**, **506**, **508**. In various embodiments, the communications interface **604** may also support communications with another electronic device (e.g., CCD **106** and/or computer **108**) in an infusion system (e.g., to upload sensor measurement values to a server or other computing device, receive control information from a server or other computing device, and the like).

The pump control module **602** generally represents the hardware, circuitry, logic, firmware and/or other component of the pump control system **600** that is coupled to the communications interface **604** and configured to determine dosage commands for operating the motor **532** to deliver fluid to the body **501** based on measurement data received from the sensing arrangements **504**, **506**, **508** and perform various additional tasks, operations, functions and/or operations described herein. For example, in exemplary embodiments, pump control module **602** implements or otherwise executes a command generation application **610** that supports one or more autonomous operating modes and calculates or otherwise determines dosage commands for operating the motor **532** of the infusion device **502** in an autonomous operating mode based at least in part on a current measurement value for a condition in the body **501** of the patient. For example, in a closed-loop operating mode, the command generation application **610** may determine a dosage command for operating the motor **532** to deliver insulin to the body **501** of the patient based at least in part on the current glucose measurement value most recently received from the sensing arrangement **504** to regulate the patient's blood glucose level to a target reference glucose value. Additionally, the command generation application **610** may generate dosage commands for boluses that are manually-initiated or otherwise instructed by a patient via a user interface element.

In exemplary embodiments, the pump control module **602** also implements or otherwise executes a personalization application **608** that is cooperatively configured to interact with the command generation application **610** to support adjusting dosage commands or control information dictating the manner in which dosage commands are generated in a personalized, patient-specific manner. In this regard, in some embodiments, based on correlations between current or recent measurement data and the current operational context relative to historical data associated with the patient, the personalization application **608** may adjust or otherwise modify values for one or more parameters utilized by the command generation application **610** when determining dosage commands, for example, by modifying a parameter value at a register or location in memory **606** referenced by the command generation application **610**. In yet other embodiments, the personalization application **608** may predict meals or other events or activities that are likely to be engaged in by the patient and output or otherwise provide an indication of the predicted patient behavior for confirmation or modification by the patient, which, in turn, may then be utilized to adjust the manner in which dosage commands are generated to regulate glucose in a manner that accounts for the patient's behavior in a personalized manner.

Still referring to FIG. **6**, depending on the embodiment, the pump control module **602** may be implemented or realized with at least one general purpose processor device, a microprocessor, a controller, a microcontroller, a state machine, a content addressable memory, an application specific integrated circuit, a field programmable gate array, any suitable programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof, designed to perform the functions described herein. In this regard, the steps of a method or algorithm described in connection with the embodiments disclosed herein may be embodied directly in hardware, in firmware, in a software module executed by the pump control module **602**, or in any practical combination thereof. In exemplary embodiments, the pump control module **602** includes or otherwise accesses the data storage element or memory **606**, which may be realized using any sort of non-transitory computer-readable medium capable of storing programming instructions for execution by the pump control module **602**. The computer-executable programming instructions, when read and executed by the pump control module **602**, cause the pump control module **602** to implement or otherwise generate the applications **608**, **610** and perform tasks, operations, functions, and processes described herein.

It should be understood that FIG. **6** is a simplified representation of a pump control system **600** for purposes of explanation and is not intended to limit the subject matter described herein in any way. For example, in some embodiments, the features and/or functionality of the motor control module **512** may be implemented by or otherwise integrated into the pump control system **600** and/or the pump control module **602**, for example, by the command generation application **610** converting the dosage command into a corresponding motor command, in which case, the separate motor control module **512** may be absent from an embodiment of the infusion device **502**.

FIG. **7** depicts an exemplary closed-loop control system **700** that may be implemented by a pump control system **520**, **600** to provide a closed-loop operating mode that autonomously regulates a condition in the body of a patient to a reference (or target) value. In this regard, the control system **700** can be utilized to regulate the delivery of insulin to the patient during an automatic basal insulin delivery operation. It should be appreciated that FIG. **7** is a simplified representation of the control system **700** for purposes of explanation and is not intended to limit the subject matter described herein in any way.

In exemplary embodiments, the control system **700** receives or otherwise obtains a target glucose value at input **702**. In some embodiments, the target glucose value may be stored or otherwise maintained by the infusion device **502** (e.g., in memory **606**), however, in some alternative embodiments, the target value may be received from an external component (e.g., CCD **106** and/or computer **108**). In one or more embodiments, the target glucose value may be calculated or otherwise determined prior to entering the closed-loop operating mode based on one or more patient-specific control parameters. For example, the target blood glucose value may be calculated based at least in part on a patient-specific reference basal rate and a patient-specific daily insulin requirement, which are determined based on historical delivery information over a preceding interval of time (e.g., the amount of insulin delivered over the preceding 24 hours). The control system **700** also receives or otherwise obtains a current glucose measurement value (e.g., the most recently obtained sensor glucose value) from the sensing arrangement **504** at input **704**. The illustrated control system **700** implements or otherwise provides proportional-integral-derivative (PID) control to determine or otherwise generate delivery commands for operating the motor **532** based at least in part on the difference between the target glucose value and the current glucose measurement value. In this regard, the PID control attempts to minimize the difference between the measured value and the target value, and thereby regulates the measured value to the desired value. PID control parameters are applied to the difference between the target glucose level at input **702** and the measured glucose level at input **704** to generate or otherwise determine a dosage (or delivery) command provided at output **730**. Based on that delivery command, the motor control module **512** operates the motor **532** to deliver insulin to the body of the patient to influence the patient's glucose level, and thereby reduce the difference between a subsequently measured glucose level and the target glucose level.

The illustrated control system **700** includes or otherwise implements a summation block **706** configured to determine a difference between the target value obtained at input **702** and the measured value obtained from the sensing arrangement **504** at input **704**, for example, by subtracting the target value from the measured value. The output of the summation block **706** represents the difference between the measured and target values, which is then provided to each of a proportional term path, an integral term path, and a derivative term path. The proportional term path includes a gain block **720** that multiplies the difference by a proportional gain coefficient, KP, to obtain the proportional term. The integral term path includes an integration block **708** that integrates the difference and a gain block **722** that multiplies the integrated difference by an integral gain coefficient, KI, to obtain the integral term. The derivative term path includes a derivative block **710** that determines the derivative of the difference and a gain block **724** that multiplies the derivative of the difference by a derivative gain coefficient, KD, to obtain the derivative term. The proportional term, the integral term, and the derivative term are then added or otherwise combined to obtain a delivery command that is utilized to operate the motor at output **730**. Various implementation details pertaining to closed-loop PID control and determining gain coefficients are described in greater detail in U.S. Pat. No. 7,402,153, which is incorporated by reference.

In one or more exemplary embodiments, the PID gain coefficients are patient-specific and dynamically calculated or otherwise determined prior to entering the closed-loop operating mode based on historical insulin delivery information (e.g., amounts and/or timings of previous dosages, historical correction bolus information, or the like), historical sensor measurement values, historical reference blood glucose measurement values, user-reported or user-input events (e.g., meals, exercise, and the like), and the like. In this regard, one or more patient-specific control parameters (e.g., an insulin sensitivity factor, a daily insulin requirement, an insulin limit, a reference basal rate, a reference fasting glucose, an active insulin action duration, pharmodynamical time constants, or the like) may be utilized to compensate, correct, or otherwise adjust the PID gain coefficients to account for various operating conditions experienced and/or exhibited by the infusion device **502**. The PID gain coefficients may be maintained by the memory **606** accessible to the pump control module **602**. In this regard, the memory **606** may include a plurality of registers associated with the control parameters for the PID control. For example, a first parameter register may store the target glucose value and be accessed by or otherwise coupled to the summation block **706** at input **702**, and similarly, a second parameter register accessed by the proportional gain block **720** may store the proportional gain coefficient, a third parameter register accessed by the integration gain block **722** may store the integration gain coefficient, and a fourth parameter register accessed by the derivative gain block **724** may store the derivative gain coefficient.

In one or more exemplary embodiments, one or more parameters of the closed-loop control system **700** are automatically adjusted or adapted in a personalized manner to account for potential changes in the patient's glucose level or insulin sensitivity resulting from meals, exercise, or other events or activities. For example, in one or more embodiments, the target glucose value may be decreased in advance of a predicted meal event to achieve an increase in the insulin infusion rate to effectively pre-bolus a meal, and thereby reduce the likelihood of postprandial hyperglycemia. Additionally or alternatively, the time constant or gain coefficient associated with one or more paths of the closed-loop control system **700** may be adjusted to tune the responsiveness to deviations between the measured glucose value and the target glucose value. For example, based on the particular type of meal being consumed or the particular time of day during which the meal is consumed, the time constant associated with the derivative block **710** or derivative term path may be adjusted to make the closed-loop control more or less aggressive in response to an increase in the patient's glucose level based on the patient's historical glycemic response to the particular type of meal.

FIG. **8** depicts an exemplary embodiment of a patient monitoring system **800**. The patient monitoring system **800** includes a medical device **802** that is communicatively coupled to a sensing element **804** that is inserted into the body of a patient or otherwise worn by the patient to obtain measurement data indicative of a physiological condition in the body of the patient, such as a sensed glucose level. The medical device **802** is communicatively coupled to a client device **806** via a communications network **810**, with the client device **806** being communicatively coupled to a remote device **814** via another communications network **812**. In this regard, the client device **806** may function as an intermediary for uploading or otherwise providing measurement data from the medical device **802** to the remote device **814**. It should be appreciated that FIG. **8** depicts a simplified representation of a patient monitoring system **800** for purposes of explanation and is not intended to limit the subject matter described herein in any way.

In exemplary embodiments, the client device **806** is realized as a mobile phone, a smartphone, a tablet computer, or other similar mobile electronic device; however, in other embodiments, the client device **806** may be realized as any sort of electronic device capable of communicating with the medical device **802** via network **810**, such as a laptop or notebook computer, a desktop computer, or the like. In exemplary embodiments, the network **810** is realized as a Bluetooth network, a ZigBee network, or another suitable personal area network. That said, in other embodiments, the network **810** could be realized as a wireless ad hoc network, a wireless local area network (WLAN), or local area network (LAN). The client device **806** includes or is coupled to a display device, such as a monitor, screen, or another conventional electronic display, capable of graphically presenting data and/or information pertaining to the physiological condition of the patient. The client device **806** also includes or is otherwise associated with a user input device, such as a keyboard, a mouse, a touchscreen, or the like, capable of receiving input data and/or other information from the user of the client device **806**.

In exemplary embodiments, a user, such as the patient, the patient's doctor or another healthcare provider, or the like, manipulates the client device **806** to execute a client application **808** that supports communicating with the medical device **802** via the network **810**. In this regard, the client application **808** supports establishing a communications session with the medical device **802** on the network **810** and receiving data and/or information from the medical device **802** via the communications session. The medical device **802** may similarly execute or otherwise implement a corresponding application or process that supports establishing the communications session with the client application **808**. The client application **808** generally represents a software module or another feature that is generated or otherwise implemented by the client device **806** to support the processes described herein. Accordingly, the client device **806** generally includes a processing system and a data storage element (or memory) capable of storing programming instructions for execution by the processing system, that, when read and executed, cause processing system to create, generate, or otherwise facilitate the client application **808** and perform or otherwise support the processes, tasks, operations, and/or functions described herein. Depending on the embodiment, the processing system may be implemented using any suitable processing system and/or device, such as, for example, one or more processor devices, central processing units (CPUs), controllers, microprocessors, microcontrollers, processing cores and/or other hardware computing resources configured to support the operation of the processing system described herein. Similarly, the data storage element or memory may be realized as a random-access memory (RAM), read only memory (ROM), flash memory, magnetic or optical mass storage, or any other suitable non-transitory short or long-term data storage or other computer-readable media, and/or any suitable combination thereof.

In one or more embodiments, the client device **806** and the medical device **802** establish an association (or pairing) with one another over the network **810** to support subsequently establishing a point-to-point or peer-to-peer communications session between the medical device **802** and the client device **806** via the network **810**. For example, in accordance with one embodiment, the network **810** is realized as a Bluetooth network, wherein the medical device **802** and the client device **806** are paired with one another (e.g., by obtaining and storing network identification information for one another) by performing a discovery procedure or another suitable pairing procedure. The pairing information obtained during the discovery procedure allows either of the medical device **802** or the client device **806** to initiate the establishment of a secure communications session via the network **810**.

In one or more exemplary embodiments, the client application **808** is also configured to store or otherwise maintain an address and/or other identification information for the remote device **814** on the second network **812**. In this regard, the second network **812** may be physically and/or logically distinct from the network **810**, such as, for example, the Internet, a cellular network, a wide area network (WAN), or the like. The remote device **814** generally represents a server or other computing device configured to receive and analyze or otherwise monitor measurement data, event log data, and potentially other information obtained for the patient associated with the medical device **802**. In exemplary embodiments, the remote device **814** is coupled to a database **816** configured to store or otherwise maintain data associated with individual patients. In some embodiments, the remote device **814** may reside at a location that is physically distinct and/or separate from the medical device **802** and the client device **806**, such as, for example, at a facility that is owned and/or operated by or otherwise affiliated with a manufacturer of the medical device **802**. For purposes of explanation, but without limitation, the remote device **814** may alternatively be referred to herein as a server.

Still referring to FIG. **8**, the sensing element **804** generally represents the component of the patient monitoring system **800** that is configured to generate, produce, or otherwise output one or more electrical signals indicative of a physiological condition that is sensed, measured, or otherwise quantified by the sensing element **804**. In this regard, the physiological condition of a patient influences a characteristic of the electrical signal output by the sensing element **804**, such that the characteristic of the output signal corresponds to or is otherwise correlative to the physiological condition that the sensing element **804** is sensitive to. In exemplary embodiments, the sensing element **804** is realized as an interstitial glucose sensing element inserted at a location on the body of the patient that generates an output electrical signal having a current (or voltage) associated therewith that is correlative to the interstitial fluid glucose level that is sensed or otherwise measured in the body of the patient by the sensing element **804**.

The medical device **802** generally represents the component of the patient monitoring system **800** that is communicatively coupled to the output of the sensing element **804** to receive or otherwise obtain the measurement data samples from the sensing element **804** (e.g., the measured glucose and characteristic impedance values), store or otherwise maintain the measurement data samples, and upload or otherwise transmit the measurement data to the remote device **814** or server via the client device **806**. In one or more embodiments, the medical device **802** is realized as an infusion device **102**, **200**, **502** configured to deliver a fluid, such as insulin, to the body of the patient. That said, in other embodiments, the medical device **802** could be a standalone sensing or monitoring device separate and independent from an infusion device (e.g., sensing arrangement **104**, **504**). It should be noted that although FIG. **8** depicts the medical device **802** and the sensing element **804** as separate components, in some embodiments, the medical device **802** and the sensing element **804** may be integrated or otherwise combined to provide a unitary device that can be worn by the patient.

In exemplary embodiments, the medical device **802** includes a control module **822**, a data storage element **824** (or memory), and a communications interface **826**. The control module **822** generally represents the hardware, circuitry, logic, firmware and/or other component(s) of the medical device **802** that is coupled to the sensing element **804** to receive the electrical signals output by the sensing element **804** and perform or otherwise support various additional tasks, operations, functions and/or processes described herein. Depending on the embodiment, the control module **822** may be implemented or realized with a general purpose processor device, a microprocessor device, a controller, a microcontroller, a state machine, a content addressable memory, an application specific integrated circuit, a field programmable gate array, any suitable programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof, designed to perform the functions described herein. In some embodiments, the control module **822** includes an analog-to-digital converter (ADC) or another similar sampling arrangement that samples or otherwise converts an output electrical signal received from the sensing element **804** into corresponding digital measurement data value. In other embodiments, the sensing element **804** may incorporate an ADC and output a digital measurement value.

The communications interface **826** generally represents the hardware, circuitry, logic, firmware and/or other components of the medical device **802** that are coupled to the control module **822** for outputting data and/or information from/to the medical device **802** to/from the client device **806**. For example, the communications interface **826** may include or otherwise be coupled to one or more transceiver modules capable of supporting wireless communications between the medical device **802** and the client device **806**. In exemplary embodiments, the communications interface **826** is realized as a Bluetooth transceiver or adapter configured to support Bluetooth Low Energy (BLE) communications.

In exemplary embodiments, the remote device **814** receives, from the client device **806**, measurement data values associated with a particular patient (e.g., sensor glucose measurements, acceleration measurements, and the like) that were obtained using the sensing element **804**, and the remote device **814** stores or otherwise maintains the historical measurement data in the database **816** in association with the patient (e.g., using one or more unique patient identifiers). Additionally, the remote device **814** may also receive, from or via the client device **806**, meal data or other event log data that may be input or otherwise provided by the patient (e.g., via client application **808**) and store or otherwise maintain historical meal data and other historical event or activity data associated with the patient in the database **816**. In this regard, the meal data include, for example, a time or timestamp associated with a particular meal event, a meal type or other information indicative of the content or nutritional characteristics of the meal, and an indication of the size associated with the meal. In exemplary embodiments, the remote device **814** also receives historical fluid delivery data corresponding to basal or bolus dosages of fluid delivered to the patient by an infusion device **102**, **200**, **502**. For example, the client application **808** may communicate with an infusion device **102**, **200**, **502** to obtain insulin delivery dosage amounts and corresponding timestamps from the infusion device **102**, **200**, **502**, and then upload the insulin delivery data to the remote device **814** for storage in association with the particular patient. The remote device **814** may also receive geolocation data and potentially other contextual data associated with a device **802**, **806** from the client device **806** and/or client application **808**, and store or otherwise maintain the historical operational context data in association with the particular patient. In this regard, one or more of the devices **802**, **806** may include a global positioning system (GPS) receiver or similar modules, components or circuitry capable of outputting or otherwise providing data characterizing the geographic location of the respective device **802**, **806** in real-time.

The historical patient data may be analyzed by one or more of the remote device **814**, the client device **806**, and/or the medical device **802** to alter or adjust operation of an infusion device **102**, **200**, **502** to influence fluid delivery in a personalized manner. For example, the patient's historical meal data and corresponding measurement data or other contextual data may be analyzed to predict a future time when the next meal is likely to be consumed by the patient, the likelihood of a future meal event within a specific time period, the likely size or amount of carbohydrates associated with a future meal, the likely type or nutritional content of the future meal, and/or the like. Moreover, the patient's historical measurement data for postprandial periods following historical meal events may be analyzed to model or otherwise characterize the patient's glycemic response to the predicted size and type of meal for the current context (e.g., time of day, day of week, geolocation, etc.). One or more aspects of the infusion device **102**, **200**, **502** that control or regulate insulin delivery may then be modified or adjusted to proactively account for the patient's likely meal activity and glycemic response.

In one or more exemplary embodiments, the remote device **814** utilizes machine learning to determine which combination of historical sensor glucose measurement data, historical delivery data, historical auxiliary measurement data (e.g., historical acceleration measurement data, historical heart rate measurement data, and/or the like), historical event log data, historical geolocation data, and other historical or contextual data are correlated to or predictive of the occurrence of a particular event, activity, or metric for a particular patient, and then determines a corresponding equation, function, or model for calculating the value of the parameter of interest based on that set of input variables. Thus, the model is capable of characterizing or mapping a particular combination of one or more of the current (or recent) sensor glucose measurement data, auxiliary measurement data, delivery data, geographic location, patient behavior or activities, and the like to a value representative of the current probability or likelihood of a particular event or activity or a current value for a parameter of interest. It should be noted that since each patient's physiological response may vary from the rest of the population, the subset of input variables that are predictive of or correlative for a particular patient may vary from other patients. Additionally, the relative weightings applied to the respective variables of that predictive subset may also vary from other patients who may have common predictive subsets, based on differing correlations between a particular input variable and the historical data for that particular patient. It should be noted that any number of different machine learning techniques may be utilized by the remote device **814** to determine what input variables are predictive for a current patient of interest, such as, for example, artificial neural networks, genetic programming, support vector machines, Bayesian networks, probabilistic machine learning models, or other Bayesian techniques, fuzzy logic, heuristically derived combinations, or the like.

A medical device of the type described herein can generate various user interface display screens that support different functions and features. For example, an insulin infusion device can generate a home screen that serves as a patient status or monitoring screen, a settings/preferences screen, a bolus delivery control screen, and the like. These and other display screens can present the user with different information, status data, notifications, patient data (e.g., glucose data), and/or other information in any desired arrangement or format.

Non-adjunctive insulin administration requires a sensor glucose (SG) value to be presented for bolus dosage estimation. The SG value should only be presented to the user when it is accurate, reliable, or otherwise trusted. A user may instead choose to use a blood glucose (BG) value from a linked blood glucose meter device (e.g., a blood glucose meter device in wireless or wired communication with the medical device). Given that there are two sources of inputs for therapy, and only one source may be used, the insulin infusion device is suitably configured to clearly indicate which glucose source is being used. To this end, the exemplary embodiment described here is controlled in an appropriate manner to avoid using a current SG value for bolus estimation when it is determined that the quality or reliability of the SG value is not sufficiently high. The exemplary embodiment also safely disambiguates SG from BG, for purposes of bolus estimation and presentation to the user.

The operating methodology described in more detail below is governed by certain rules when handling BG and SG values. For example, when a BG value is provided to the system, that value is displayed on a bolus delivery control screen until the BG value is expired (e.g., after a designated period of time, such as 12 minutes). A unique and visually distinguishable icon is used to indicate that the displayed value is a BG value. If the user fails to make a bolus delivery selection within a predefined period of time (e.g., 12 minutes or any other period of time), the bolus delivery feature will timeout.

In accordance with another operating rule, when an SG value is trusted by the system and there is no recent BG entry, the bolus delivery control screen includes the current SG value with a corresponding icon in a manner that is visually distinguishable from a displayed BG value. The SG value displayed within the bolus delivery screen cannot be modified via the user interface of the insulin infusion device.

In accordance with another operating rule, if there is a sudden spike in SG readings (e.g., the SG increases at a rate that is higher than a predetermined threshold value) that cannot be attributed to carbohydrate ingestion or other physiological processes, the current SG value is assumed to be temporarily unsuitable for non-adjunctive therapy. In that instance, no alert is required, but the SG value is not presented on the bolus delivery control screen, and the SG value is not used to calculate a bolus estimate.

Accordingly, the insulin infusion device supports a user interface associated with fully non-adjunctive bolus estimation. The current SG value is intuitively displayed in the bolus delivery control screen when it is a stable/trusted value. Otherwise, the SG value is removed from the bolus delivery control screen without generating a user alert. If the user desires to administer a manual bolus, then user can provide a BG value to be used for bolus estimation. The display screens and user interface features are designed such that the SG value is clearly disambiguated from the BG value. This avoids user confusion and potential bolus estimation errors.

FIG. **9** is a flow chart that illustrates an exemplary embodiment of a process **900** for operating a medical device that regulates delivery of a fluid medication to a user. The process **900** may be performed by an insulin infusion device of the type described above or any other medical device. The process **900** receives meter-generated values that are indicative of a physiological characteristic of the user, wherein the generated values are produced in response to operation of an analyte meter device. For the exemplary implementation described here, the medical device is an insulin infusion device, the fluid medication is insulin, the physiological characteristic of interest is blood glucose, and the meter-generated values are BG values obtained from a blood glucose meter device (e.g., a BG fingerstick device) that generates BG measurements from a blood sample taken from the user. Thus, the exemplary embodiment of the process **900** receives BG values (e.g., once a day, every 12 hours, or as often as desired by the user), either directly from a linked BG meter or via manual data entry by a user or caregiver at the insulin infusion device (task **902**). The insulin infusion device assumes that recently received BG measurements (whether they are user-entered or received directly from a BG meter device) are accurate and trustworthy.

The process **900** also obtains sensor-generated values that are indicative of the same physiological characteristic of the user, wherein the sensor-generated values are produced in response to operation of a continuous analyte sensor device. For the exemplary insulin infusion device implementation described here, the sensor-generated values are SG values obtained from a continuous glucose monitor or sensor (or calculated from sensor data obtained from a continuous glucose monitor or sensor) that is worn by the user. Thus, the exemplary embodiment of the process **900** obtains SG values periodically, e.g., every five minutes, every ten minutes, or any other desired period of time (task **904**). In some embodiments, tasks **902** and **904** are performed independently of one another. For example, task **904** may be performed more often than task **902**, or tasks **902** and **904** may be performed serially in any order or concurrently.

The process **900** determines how to use the BG value and/or the SG value for display purposes and for therapy dosage and delivery purposes. To this end, the exemplary embodiment of the process **900** checks for the presence of a valid BG value, e.g., a valid meter-generated value (query task **906**). For this particular implementation, a current BG value is deemed to be "valid" until it expires after an expiration time period. The expiration time period may vary from one embodiment to another. For this particular example, BG values have a valid lifespan of only 12 minutes; stale BG values are not used. Thus, if the process **900** determines that a valid BG value is available (the "Yes" branch of query task **906**), then the device is controlled in an appropriate manner to operate in a first mode, e.g., as described in further detail with respect to FIG. **10** below (task **908**). In accordance with the embodiment described here, the device is operated in the first mode when a valid meter-generated BG value is available, regardless of the availability of a sensor-generated SG value, and regardless of the quality, accuracy, or trustworthiness of the current SG value (if one is available).

FIG. **10** is a flow chart that illustrates operation of the insulin infusion device in the first mode. The first mode operation process **1000** depicted in FIG. **10** can be performed at task **908** of the process **900**.

In this example, a "fresh" BG value is assumed to be accurate and trustworthy. Accordingly, the process **1000** displays the valid BG value on a user monitoring screen of the device (task **1002**). This BG value remains displayed on the user monitoring screen while it remains valid. Once the BG value expires or is otherwise deemed to be invalid, it is removed from the user monitoring screen (e.g., ceased to be displayed within the user monitoring screen). In some embodiments, the user monitoring screen is a home screen of the insulin infusion device, and the home screen may include additional information if so desired, such as other patient data, status indicators, etc. In this regard, FIG. **11** is a schematic representation of a user monitoring screen **1100** on an insulin infusion device, with a current and valid meter-generated BG value **1102** displayed thereon. The BG value **1102** can be displayed with a "BG" label **1104** to make it obvious that the displayed value is indeed a BG value (rather than an SG value). Moreover, the process **1000** displays the BG value using visually distinguishable characteristics, which may also be used for displaying the "BG" label **1104** and for displaying the units of the BG value (mg/dL). For example, any one or more of the following visually distinguishable characteristics can be utilized for displaying the BG value: color; font design; font size; font characteristics such as bold, italic, or outlined; animation such as a flashing display or a moving display; fill pattern or stippling; level of transparency; and an accompanying icon (such as a blood drop).

Referring back to FIG. **10**, the process **1000** also displays the valid BG value on a therapy delivery control screen of the device (task **1004**). The BG value remains displayed on the therapy delivery control screen while it remains valid. Once the BG value expires or is otherwise deemed to be invalid, it is removed from the therapy delivery control screen. For this particular embodiment, the therapy delivery control screen is an insulin bolus delivery control screen of the insulin infusion device, and the bolus delivery control screen may include additional information related to an estimated bolus dosage and the operation of the bolus delivery function. In this regard, FIG. **12** is a schematic representation of a therapy delivery control screen **1200** on an insulin infusion device, with the current and valid BG value **1202** displayed thereon. The BG value **1202** can be displayed with a "BG" label **1204** to make it obvious that the displayed value is indeed a BG value (rather than an SG value). In addition, the BG value **1202** can be displayed with a visually distinguishable and contextually relevant icon **1206** to further indicate that the displayed value is a BG value rather than an SG value. For this example, the icon **1206** resembles a drop of blood, and the icon **1206** is colored red.

Notably, the process **1000** displays the BG value **1202** using the same (or substantially similar) visually distinguishable characteristics used to display the BG value **1102** on the user monitoring screen **1100**. The same visually distinguishable characteristics may also be used for displaying the "BG" label **1204** and for displaying the units of the BG value (mg/dL). Using the same visually distinguishable characteristics for the BG value across different user interface screens or features makes it easy for the user to interpret and recognize the source of the displayed glucose measurement. Although this description focuses on the user monitoring screen and the therapy delivery control screen, consistent visual characteristics ("look and feel" aspects) can be used across any number of display screens generated by the device.

Referring back to FIG. **10**, the process **1000** inhibits the display of any SG value on the user monitoring screen and on the therapy delivery control screen (task **1006**). In this regard, if a valid BG value is available, then the device relies on that measurement, whether or not a current and accurate SG value is also available. Thus, preventing display of an available SG value under these conditions is intuitive and less confusing for users.

The process **1000** continues by calculating therapy dosage (if needed) for delivery, based on the valid meter-generated BG value (task **1008**). For this example, an insulin bolus is calculated at task **1008**, and the calculated bolus amount is displayed on the therapy delivery control screen. In this regard, the therapy delivery control screen **1200** shown in FIG. **12** includes a calculated insulin bolus of 0.8 Units. Thus, the valid BG value serves as an input or parameter for purposes of estimating an appropriate insulin bolus to maintain the user's blood glucose level within a desired target range.

In some embodiments, the calculated bolus amount can be automatically or manually administered. For example, the bolus can be automatically delivered if automatic delivery mode is supported and active. Accordingly, during operation in the first mode, the process **1000** enables an automatic therapy delivery function of the device (task **1010**). Consequently, if the user fails to manually administer the calculated bolus amount, the automatic delivery function will take appropriate action to deliver the bolus in a timely manner. To this end, the process **1000** may automatically control the operation of the device to regulate delivery of the fluid medication (insulin) from the device, in accordance with the calculated therapy dosage (task **1012**).

Returning to FIG. **9** and the description of the process **900**, if a valid BG value is unavailable (the "No" branch of query task **906**), then the process **900** checks the current SG value to determine a measure of quality. The quality of the current SG value can be determined or calculated using any appropriate methodology. For example, the current SG value can be compared against historical SG measurements, historical BG measurements, the most recent BG value, or the like. Additionally or alternatively, the quality of the current SG value can be determined using a "self-diagnostic" technique that considers the age of the continuous glucose sensor, SG measurement trends, electrical noise in the raw sensor signals, etc. In accordance with certain embodiments, the process **900** determines the quality of the SG measurements using the methodology described in more detail below.

Although the quality of SG measurements can be expressed in any suitable manner, the exemplary embodiment of the process **900** considers "high quality" SG measurements to be the best quality (e.g., above a high-quality threshold) and, therefore, appropriate for purposes of glucose monitoring, for therapy dosage calculation, and for controlling the delivery of therapy. The process **900** considers "monitor quality" SG measurements to be appropriate for glucose monitoring only, wherein monitor quality SG measurements are less desirable than high quality SG measurements, yet still suitable for certain non-therapy related functions (e.g., below the high-quality threshold and above a low-quality threshold). If the quality of an SG measurement is deemed to be less than monitor quality (e.g., below the low-quality threshold), then that SG value is neither displayed nor used for therapy related functions.

If the process **900** determines that the current SG value satisfies "high quality" criteria, e.g., quality above the high-quality threshold (the "Yes" branch of query task **910**), then the device is controlled in an appropriate manner to operate in a second mode (task **912**). In accordance with the embodiment described here, the device is operated in the second mode when a valid meter-generated BG value is unavailable, and when the current sensor-generated SG value is determined to be of high quality.

FIG. **13** is a flow chart that illustrates operation of the insulin infusion device in the second mode. The second mode operation process **1300** depicted in FIG. **13** can be performed at task **912** of the process **900**. The second mode relies on the high quality SG value, which is currently available for use. Accordingly, the process **1300** displays the current SG value on the user monitoring screen of the device (task **1302**). This SG value remains displayed on the user monitoring screen until it is refreshed. FIG. **14** is a schematic representation of a user monitoring screen **1400** on the insulin infusion device, with the current SG value **1402** displayed thereon. The SG value **1402** can be displayed with an "SG" label (not shown) to make it obvious that the displayed value is indeed an SG value (rather than a BG value). The example shown in FIG. **14** displays glucose trend arrows **1404** near the displayed SG value **1402** to indicate whether the user's blood glucose level is increasing or decreasing (e.g., compared to previous glucose level measurements). Moreover, the process **1300** displays the SG value **1402** using visually distinguishable characteristics, which may also be used for displaying the "SG" label, the trend arrows **1404**, and the units of the SG value (mg/dL). The embodiment described here uses color as the visually distinguishable characteristic. In some embodiments, however, any one or more of the following characteristics can be utilized for displaying the SG value: color; font design; font size; font characteristics such as bold, italic, or outlined; animation such as a flashing display or a moving display; fill pattern or stippling; level of transparency; and an accompanying icon. Notably, SG values and BG values are displayed using different visually distinguishable characteristics, such that the user can quickly and easily observe whether the displayed measurement is a BG value or an SG value. For example, BG values and related information can be rendered in a white or yellow font, while SG values and related information can be rendered in an obviously contrasting color, such as blue, cyan, or purple.

Referring back to FIG. **13**, the process **1300** also displays the current SG value on the therapy delivery control screen of the device (task **1304**). The SG value remains displayed on the therapy delivery control screen until it gets refreshed, and it cannot be modified via the user interface of the device. FIG. **15** is a schematic representation of a therapy delivery control screen **1500** on an insulin infusion device, with the current (and high quality) SG value **1502** displayed thereon. The SG value **1502** can be displayed with an "SG" label **1504** to make it obvious that the displayed value is indeed an SG value (rather than a BG value). In addition, the SG value **1502** can be displayed with a visually distinguishable and contextually relevant icon **1506** to further indicate that the displayed value is an SG value rather than a BG value. For this example, the icon **1506** resembles a plot or signal waveform, and the icon **1506** is colored to match the color of the displayed SG value **1502**.

Notably, the process **1300** displays the SG value **1502** using the same (or substantially similar) visually distinguishable characteristics used to display the SG value **1402** on the user monitoring screen **1400**. The same visually distinguishable characteristics may also be used for displaying the "SG" label **1504** and for displaying the units of the SG value (mg/dL). Using the same visually distinguishable characteristics for the SG value across different user interface screens or features makes it easy for the user to interpret and recognize the source of the displayed glucose measurement. Although this description focuses on the user monitoring screen and the therapy delivery control screen, consistent visual characteristics ("look and feel" aspects) can be used across any number of display screens generated by the device.

Referring back to FIG. **13**, the process **1300** inhibits the display of any BG value on the user monitoring screen and on the therapy delivery control screen (task **1306**). In this regard, if a valid BG value is unavailable, then the device only considers a current (e.g., the most recent) and accurate SG value for display purposes.

The process **1300** continues by calculating therapy dosage (if needed) for delivery, based on the high-quality sensor-generated SG value (task **1308**). For this example, an insulin bolus is calculated at task **1308**, and the calculated bolus amount is displayed on the therapy delivery control screen. In this regard, the therapy delivery control screen **1500** shown in FIG. **15** includes a calculated insulin bolus of 0.8 Units. Thus, the high quality SG value serves as an input or parameter for purposes of estimating an appropriate insulin bolus to maintain the user's blood glucose level within a desired target range.

In some example, the calculated bolus amount can be manually administered or automatically delivered if automatic delivery mode is supported and active. Accordingly, during operation in the second mode, the process **1300** enables the automatic therapy delivery function of the device (task **1310**). Consequently, if the user fails to manually administer the calculated bolus amount, the automatic delivery function will take appropriate action to deliver the bolus in a timely manner. To this end, the process **1300** may automatically control the operation of the device to regulate delivery of the fluid medication (insulin) from the device, in accordance with the calculated therapy dosage (task **1312**).

Returning to FIG. **9** and the description of the process **900**, if the current SG value does not satisfy the "high quality" criteria (the "No" branch of query task **910**), but satisfies "monitor quality" criteria (the "Yes" branch of query task **914**), then the device is controlled in an appropriate manner to operate in a third mode (task **916**). In accordance with the embodiment described here, the device is operated in the third mode when a valid meter-generated BG value is unavailable, and when the current sensor-generated SG value is determined to be of sufficient quality for user monitoring purposes but potentially unsuitable for calculating therapy dosage.

FIG. **16** is a flow chart that illustrates operation of the insulin infusion device in the third mode. The third mode operation process **1600** depicted in FIG. **16** can be performed at task **916** of the process **900**. The third mode relies on the monitor quality SG value, which is currently available for use. Accordingly, the process **1600** displays the current SG value on the user monitoring screen of the device (task **1602**). This SG value remains displayed on the user monitoring screen until it is refreshed. The above description of the user monitoring screen **1400** (see FIG. **14**) also applies to this scenario because the monitor quality SG value is displayed in a similar fashion, with the same visually distinguishable characteristics described previously in connection with the exemplary display shown in FIG. **14**.

While operating in the third mode, the device inhibits the display of the current SG value on the therapy delivery control screen (task **1604**). In addition, the process **1600** inhibits the display of any BG value on the therapy delivery control screen (task **1606**). Instead, the device is operated to display an appropriate message, notification, or indication on the therapy delivery control screen, wherein the displayed content indicates that no suitable measurement of the physiological characteristic of the user is available. For this particular example, the process **1600** displays a message such as "No Glucose" or "No Glucose Available" on the therapy delivery control screen (task **1608**). FIG. **17** is a schematic representation of a therapy delivery control screen **1700** on an insulin infusion device, with neither a BG value nor an SG value displayed thereon. Instead, the therapy delivery control screen **1700** includes a "No Glucose" message or field **1702** that lets the user know that no suitable glucose measurement is available for purposes of calculating an estimated bolus. Consequently, the therapy delivery control screen **1700** indicates a bolus amount of 0.0 Units under these conditions.

Referring back to FIG. **16**, the process **1600** inhibits the use of the current SG value for purposes of calculating therapy dosage for delivery (task **1610**). Although a monitor quality SG value is suitable for use as a general indicator of the user's glucose level, the process **1600** assumes that it is potentially unsuitable for use in calculating a precise insulin bolus amount. Accordingly, the process **1600** operates the device in the third mode to disable the automatic therapy delivery function (task **1612**). For the embodiment described here, task **1612** ensures that correction boluses of insulin are not administered while the insulin infusion device is operating in the third mode.

The process **1600** may continue by prompting the user to obtain a new meter-generated BG value (task **1614**), which can be used to update the user monitoring screen and the therapy delivery control screen. Moreover, a fresh BG value can be used to calculate an estimated bolus and to reactivate the automatic therapy delivery feature. Additionally or alternatively, the process **1600** may generate a reminder, message, or notification to prompt the user to check the integrity of the sensor device, to recalibrate the sensor device, to replace the sensor device with a new unit, or the like.

Referring again to FIG. **9**, if the process **900** determines that the current SG value does not satisfy the designated "monitor quality" criteria (the "No" branch of query task **914**), then the process **900** generates an appropriate alert, message, or notification regarding the need to take some form of corrective action (task **918**). For example, the device may generate an alert to remind the user to take one or more of the following actions: obtain/enter a new BG value; check the integrity of the currently deployed sensor device; recalibrate the currently deployed sensor device; check the data communication functionality of the currently deployed sensor device; replace the sensor device with a new unit; or the like.

The process **900** is performed in an ongoing manner that contemplates updating of the BG value and/or the SG value over time. The dashed lines in FIG. **9** indicate how the process **900** is repeated as needed to receive and process new BG and SG values.

Automated insulin infusion systems that use feedback from a continuous glucose monitor (CGM) to adjust insulin dosing need to implement safety features to mitigate risk of over-delivery and hypoglycemia under certain glucose sensor conditions. These mitigations may employ one or more of the following technology components: (1) detection and rating of CGM measurement quality for use in automatic insulin dosing; (2) a set of therapy adjustments that are appropriate for each level of sensor quality; (3) a set of system alerts or other user interface (UI) notifications that guide the user to the appropriate action if needed. An example of an insulin infusion system that utilizes a sensor quality metric to adjust therapy delivery modes is described above.

Sensor Quality—A high quality CGM/sensor measurement is needed to realize the full advantages of an automated insulin infusion system to govern basal and bolus insulin deliveries. The sensor quality metric may be determined using known factors that may affect sensor accuracy. Examples of these factors include, without limitation: (1) sensor age that has known correlations to measurement accuracy; (2) measurement noise in the CGM electronics and/or raw sensor signals; (3) a sudden sharp rise or fall in sensor measurement that cannot be attributed to a natural physiological condition.

In accordance with an exemplary embodiment, the sensor quality metric may be mapped onto a scale (e.g., a scale of 1-10, or Low/Medium/High values) that provides different quality grades that can be used to adjust the therapy. The determination of the specific grade should be associated with the potential risk of providing automated therapy given the expected level of sensor error as a result of the underlying condition. For example, transient measurement noise may result in moderate CGM measurement error, so it may correspond to a "medium" sensor quality metric, whereas a sudden, discontinuous jump or drop in a CGM measurement may correspond to a "low" sensor quality metric for purposes of this description.

The sensor quality metric may also depend on characteristics of historical CGM values in a time series. For example, previous CGM values for a moving window of time can be analyzed and compared against the current value. As another example, an average of historical CGM values obtained at or near the same time of day can be analyzed and compared against the current value (obtained at the time of day under analysis). Accordingly, if a sufficient amount of historical values are not available, this condition itself may result in a conservative sensor quality rating until enough historical values are be recorded.

Therapy Adjustments—Once a sensor quality metric is determined, an adjustment to the control algorithm or methodology that governs automated insulin infusion may be necessary to mitigate risks of over or under delivery of insulin. In some embodiments, the specific type of adjustment is dependent on the design of the automated infusion algorithm.

As an example, consider an automated infusion algorithm that uses CGM measurements to make real-time adjustments to basal insulin and provide additional bolus insulin during times of rapidly rising glucose. Furthermore, this algorithm contains a safe fallback delivery mode that provides a constant basal rate for times when the CGM measurement is not available. In such a system, the following cases may be considered for therapy adjustment:

Case 1: "High" CGM/sensor quality metric—The algorithm may use its full authority of basal and bolus insulin based on the CGM measurements.

Case 2: "Medium" CGM/sensor quality metric—Allow only basal insulin delivery to be determined using the CGM but cease or otherwise limit the delivery of bolus insulin.

Case 3: "Low" CGM/sensor quality metric—Ignore the CGM altogether and revert to the safe fallback delivery mode until the sensor quality recovers.

The three cases listed above are representative examples for a hypothetical automated insulin infusion system. A different algorithm design would require therapy adjustments that are matched to the algorithm's dosing rules and/or other factors.

System Alerts and Notifications—System alerts and notifications represent another component to help manage risk while balancing therapy effectiveness and user burden. It is most desirable to maintain acceptable therapy without adding the burden of system alerts that interrupt the user. However, in some cases an alert is necessary to further mitigate risks related to poor CGM quality or to guide the user the action needed to recover optimal therapy.

For example, a particular CGM quality condition may be known to be transient in nature and generally recover without any intervention. In this case it may be appropriate for the system to make the therapy adjustment without notifying the user. However, a condition may be included to notify the user if the CGM quality is not fully recovered after a specified period of time.

As another example, a different CGM quality condition may be known to require a calibration using an external blood glucose measurement to recover. In this case it would be appropriate to alert the user that a CGM calibration is required once this condition occurs.

As mentioned above, the sensor quality metric can be scaled in any desirable manner. In accordance with an exemplary embodiment, the sensor quality metric can be "unknown" or "uncertain" or it can indicate low, medium, or high sensor quality. Table 1 indicates all of the sensor quality metrics for such an implementation, along with their related therapy actions, and system alerts.

TABLE 1

Sensor Quality and Corresponding Actions

Sensor Quality Metric	Definition	Cause	Therapy Action	User Alert
Uncertain	Sensor quality cannot be determined	Insufficient sensor data collected for quality assessment	Deliver automatic basal insulin only; No automatic bolus	None

TABLE 1-continued

Sensor Quality and Corresponding Actions

Sensor Quality Metric	Definition	Cause	Therapy Action	User Alert
Low	Sensor quality is not reliable for governing therapy	Rapid change due to hardware issues	Revert to safe fallback mode	Request BG measurement for calibration
Medium	Sensor quality is appropriate for conservative therapy	New or old sensor; Transient measurement noise; Low sensor sensitivity	Deliver automatic basal insulin; Reduced authority of automatic boluses	None
High	Sensor quality is good for full therapy	N/A	Full automated basal and bolus insulin therapy	None

FIG. **18** is a flow chart that illustrates an exemplary embodiment of a process **1800** for controlling operation of a medical device to regulate therapy actions based on sensor quality. The process **1800** obtains a current sensor-generated value that is indicative of a physiological characteristic of the user, where the value is produced in response to operation of a continuous analyte sensor device. The embodiment presented here relates to an insulin infusion system that includes or cooperates with a continuous glucose sensor—the physiological characteristic is a glucose level.

The process **1800** obtains a current SG value from a CGM sensor device (task **1802**). The process **1800** calculates, receives, or otherwise obtains a sensor quality metric for the CGM sensor device, where the sensor quality metric indicates accuracy, reliability, and/or trustworthiness of the current sensor-generated SG value (task **1804**). In accordance with certain embodiments, the sensor quality metric is calculated by the CGM sensor device, which communicates the calculated sensor quality metric to one or more destination devices as needed (for example, the calculated sensor quality metric can be sent from the CGM sensor device to the insulin infusion device, to a glucose monitor device, to a mobile device running a suitably configured mobile app, or the like). Alternatively, or additionally, the sensor quality metric can be calculated by one or more devices other than the CGM sensor device, based on raw sensor signals or information generated at the CGM sensor device. For example, the CGM sensor device can provide its electrical output (such as electrical current values or voltages) to the insulin infusion device, which then calculates the sensor quality metric based on the provided electrical output values.

The process **1800** continues by adjusting therapy actions of the insulin infusion device in response to the sensor quality metric, to configure a quality-specific operating mode of the insulin infusion device (task **1806**), as described in more detail below with reference to FIG. **20**. Thus, therapy-related functions, features, and/or operations of the medical device (the insulin infusion device) are altered based on the calculated sensor quality metric, e.g., high-quality, medium-quality, low-quality, etc. As shown in Table 1, conservative or aggressive insulin therapy options can be enabled/disabled in an ongoing manner, depending on the current state of the sensor quality metric. Moreover, the process **1800** manages the generation of user alerts at the medical device in response to the calculated sensor quality metric (task **1808**). In this regard, the process **1800** controls the insulin infusion device (and/or other user devices) to generate, inhibit, or otherwise regulate user alerts, based on the current state of the sensor quality metric. In some embodiments, task **1808** manages alerts by generating user alerts when the calculated sensor quality metric satisfies designated alert-generating criteria, and inhibits user alerts when the calculated sensor quality metric fails the designated alert-generating criteria. The alert-generating criteria can be designated to reduce unwanted or annoyance alerts, alarms, and notifications. For example, the alert-generating criteria may inhibit user alerts if the sensor quality metric is "better" than low. As another example, the alert-generating criteria may permit user alerts if the sensor quality metric is low, or if the system determines that the sensor is at its end of life or has lost communication with the medical device. This provides a better user experience with less nuisance alerts and less worrisome notifications.

The process **1800** continues by regulating delivery of fluid medication (e.g., insulin) from the medical device, in accordance with the current SG value and in accordance with the quality-specific operating mode of the medical device (task **1810**). In other words, the delivery of the fluid medication is controlled in response to the current sensor quality metric, which determines the quality-specific operating mode to be used, which results in an adjustment of certain specified therapy actions (see Table 1). For this particular implementation, task **1810** adjusts the therapy actions of the insulin infusion device such that aggressiveness of the insulin delivery therapy is proportional to the quality of the current SG value, as indicated by the calculated sensor quality metric, as described in more detail below with reference to FIG. **20**. Depending on the particular application and the type of medical device, the therapy actions can be adjusted, controlled, or regulated in a different manner using any desired methodology or algorithm that is driven by values of the sensor quality metric. The process **1800** can be repeated in an ongoing manner to contemplate updated SG values and their corresponding sensor quality metrics for purposes of adjusting the therapy actions over time.

FIG. **19** is a block diagram that illustrates the generation of a sensor quality metric in accordance with an exemplary embodiment. FIG. **19** depicts sensor quality calculation logic **1900** that calculates the sensor quality metric **1902** from one or more data inputs. The sensor quality calculation logic **1900** may reside and be executed at: the CGM sensor device; the insulin infusion device; a user monitoring device; a mobile device; a smart device or appliance; a cloud-based system, device, or service; a computing system or device onboard a vehicle; a tablet, desktop, or portable computer; or the like. Although not always required, the exemplary embodiment presented here calculates the sensor quality metric **1902** only from information, data, or signals generated by or derived from the continuous analyte sensor device. In other words, the data inputs of the sensor quality calculation logic **1900** are generated by the sensor device or are derived/calculated from data generated by the sensor device, and no information from external calibrating devices or information from ancillary devices is processed by the sensor quality calculation logic **1900** to obtain the sensor quality metric **1902**. In this regard, the continuous analyte sensor device can generate its own sensor quality metric **1902** in an "isolated" and self-diagnosing manner without relying on any additional information obtained from another device or system. Alternatively, the continuous analyte sensor device can provide its internally produced or calculated information to a compatible destination device, which then computes the sensor quality metric **1902** using only the information obtained from the sensor device.

In some examples, the data input utilized by the sensor quality calculation logic **1900** may be chosen to suit the needs and requirements of the particular medical device system, the intended application, and/or the specific embodiment. The example shown in FIG. **19** processes at least the following data inputs: sensor age data **1904**; raw sensor signal values **1906**; and/or historical sensor-generated values **1908** produced in response to operation of the continuous analyte sensor device. As mentioned above, these three data inputs are generated by the sensor device or are derived from information/data generated by the sensor device.

The sensor age data **1904** indicates a chronological age, operating life or "runtime" of the sensor device, the amount of time since deployment of the sensor device, or the like. In this regard, the sensor age data **1904** can be based on the date/time of manufacture, the date/time of initial deployment on the body of the user, the date/time following initialization or warmup of the sensor device following deployment, etc. Preferred implementations base the age of the sensor device on a time immediately following initialization or warmup of the deployed sensor device, which can be determined or marked by the sensor device in certain implementations. The sensor device can keep track of its age and update the sensor age data **1904** in an ongoing manner over time. Alternatively or additionally, the sensor device can mark and report the initial date/time (following warmup), to enable a destination device to keep track of the sensor age and update the sensor age data **1904** as time progresses.

The raw sensor signal values **1906** correspond to the raw signal output of the continuous analyte sensor device, which is produced while the sensor device is monitoring the physiological characteristic of interest. In certain embodiments, the raw sensor signal values **1906** are electrical current and/or electrical voltage measurements. For the continuous glucose sensor example described here, the raw sensor signal values **1906** are electrical current readings that are sometimes referred to as "ISIG" values. The raw sensor signal values **1906** are processed or converted into the monitored analyte levels, such as blood glucose values. To this end, the sensor-generated values **1908** depicted in FIG. **19** represent the usable sensor values that are derived from, calculated from, or converted from the raw sensor signal values **1906**. The methodology described here considers a number of historical sensor-generated values **1908** as needed to generate the sensor quality metric **1902** that is associated with the current sensor value.

In certain embodiments, the sensor quality calculation logic **1900** calculates the sensor quality metric **1902** based on: the sensor age data **1904**; measurement noise of the raw signal output of the continuous analyte sensor device; and changes in the sensor-generated values **1908** that cannot be attributed to a natural physiological condition of the user. The sensor age data **1904** is considered because accuracy of a newly deployed sensor device usually fluctuates for a short period of time immediately following the initialization or warmup period. Measurement noise in the raw sensor signal values **1906** can be caused by various conditions, such as physical movement of the sensor device, dislodging of the embedded sensor element, sudden unpredictable changes in physiology, ingress of water or other substances at the sensor site, or the like. The raw sensor signal values **1906** are usually relatively stable over "long" periods of time such as five minutes. If, however, the sensor quality calculation logic **1900** detects high variation (measurement noise) in the raw sensor signal values **1906**, then the corresponding sensor measurements can be designated as low quality. Similarly, if the sensor-generated values **1908** exhibit sharp changes, spikes, or unrealistic measurements that do not correspond to normal physiological changes or conditions, then the sensor quality calculation logic **1900** can flag those sensor values as low quality or disregard them.

The sensor quality calculation logic **1900** may consider any of the input data items individually or in any combination to generate the sensor quality metric **1902**. As mentioned previously, the sensor quality metric **1902** can be expressed in any desired format, using any desired range, scale, or domain. For the exemplary embodiment presented here, the sensor quality metric **1902** is calculated to be a number between 0 and 10 (inclusive), but only four of the available metric values are mapped to the quality states indicated in Table 1: Uncertain; Low; Medium; and High. In other embodiments, more or less than four quality states may be utilized. The sensor quality metric **1902** is generated and formatted in an appropriate manner for compatibility with a fluid medication delivery device, such that therapy actions of the fluid medication delivery device are adjusted in response to the calculated sensor quality metric.

The sensor quality calculation logic **1900** performs a method of assessing operational quality of the continuous analyte sensor device, with the sensor quality metric **1902** serving as an indication of the quality. The sensor quality metric **1902** can be utilized to regulate, control, or adjust certain functions or features of an associated medical device that regulates the delivery of therapy to a patient. In this regard, FIG. **20** is a flow chart that illustrates operation of an insulin infusion device in accordance with an exemplary embodiment (process **2000**) for sensor quality calculation logic **1900**. The following description of the process **2000** assumes that the insulin infusion device receives or generates sensor quality metrics with corresponding SG values, as described above. Accordingly, the illustrated embodiment of the process **2000** begins by processing the current value of the sensor quality metric (task **2002**). For this particular implementation, the process **2000** checks whether the sensor quality metric indicates Uncertain quality (query task **2004**), High quality (query task **2012**), Medium quality (query task **2020**), or Low quality (query task **2028**).

When the sensor quality metric indicates Uncertain quality (the "Yes" branch of query task **2004**), the process **2000** adjusts certain therapy actions of the insulin infusion device to configure an operating mode that is appropriate for the Uncertain quality status. More specifically, when the sensor quality metric indicates Uncertain quality, the process **2000** enables automatic basal insulin delivery by the insulin infusion device (task **2006**), disables an automatic bolus delivery feature of the insulin infusion device (task **2008**), and inhibits generation of any user alert related to the current sensor-generated value having Uncertain quality (task **2010**). The therapy adjustments made for this particular operating mode are appropriate under the assumption that the sensor quality metric will be determined in the near future. Thus, no user alert is generated, but the automatic bolus delivery function is temporarily disabled.

When the sensor quality metric indicates High quality, e.g., the sensor quality metric is greater than or equal to a high threshold value, such as 7 (the “Yes” branch of query task **2012**), the process **2000** adjusts certain therapy actions of the insulin infusion device to configure an appropriate high quality operating mode. More specifically, when the sensor quality metric indicates High quality, the process **2000** enables automatic basal insulin delivery by the insulin infusion device (task **2014**), enables the automatic bolus delivery feature (task **2016**), and inhibits generation of any user alert related to the current sensor-generated value having high quality (task **2018**). The therapy adjustments made for this high quality operating mode are appropriate under the assumption that the sensor device is operating in a normal and accurate manner. To this end, no user alert is generated, and both automatic basal delivery and automatic bolus delivery remain active and enabled.

When the sensor quality metric indicates Medium quality, e.g., the sensor quality metric is between a low threshold value (such as 3) and a high threshold value (such as 7) (the “Yes” branch of query task **2020**), the process **2000** adjusts certain therapy actions of the insulin infusion device to configure an appropriate medium quality operating mode. More specifically, when the sensor quality metric indicates Medium quality, the process **2000** enables automatic basal insulin delivery by the insulin infusion device (task **2022**), enables a restricted automatic bolus delivery feature (task **2024**), and inhibits generation of any user alert related to the current sensor-generated value having medium quality (task **2026**). The therapy adjustments made for this medium quality operating mode are appropriate under the assumption that the sensor device is operating in a manner that can still support a modified automatic bolus delivery function. Accordingly, no user alert is generated and automatic basal delivery remains active. However, the automatic bolus delivery function is modified to be less aggressive than usual. For example, the amount of insulin delivered by the automatic bolus delivery function may be limited or capped by some amount, or the bolus amount that is calculated from the current SG value may be reduced by a certain percentage as a safety factor. As another example, when the sensor quality metric indicates Medium quality, the insulin infusion device may be controlled in a way that places an upper limit on the current SG value for purposes of calculating and administering an automatic bolus. In accordance with certain embodiments, when the sensor quality metric indicates Medium quality, a maximum SG value is utilized for purposes of bolus calculation (e.g., 250 mg/dL)— if the current SG value is higher than the maximum allowable SG value, then the actual SG value is disregarded for purposes of automatic bolus calculation. This methodology reduces the likelihood of delivering too much insulin when the reliability or quality of the continuous glucose sensor device is potentially questionable.

When the sensor quality metric indicates Low quality, e.g., the sensor quality metric is less than or equal to a low threshold value, such as 3 (the “Yes” branch of query task **2028**), the process **2000** adjusts certain therapy actions of the insulin infusion device to configure an appropriate low quality operating mode. More specifically, when the sensor quality metric indicates Low quality, the process **2000** enables a safe basal insulin delivery mode of the insulin infusion device (task **2030**), disables the automatic bolus delivery feature (task **2032**), and generates a user alert to prompt the user to take corrective action, such as obtaining a new blood glucose meter value for sensor calibration (task **2034**). The therapy adjustments made for this low quality operating mode result in conservative insulin therapy. To this end, the normal basal insulin delivery profile for the user may be adjusted to be generally less aggressive, or the basal delivery profile may be adjusted to be a flat profile that merely provides a baseline amount of basal insulin over time. Moreover, automatic bolus delivery is suspended until the sensor quality metric improves.

As outlined above, low aggressiveness in the fluid medication therapy is provided when the sensor quality metric is low (e.g., at or below a low threshold value), medium aggressiveness is provided when the sensor quality metric is medium (e.g., between the low threshold value and a high threshold value), and high aggressiveness is provided when the sensor quality metric is high (e.g., at or above the high threshold value). Depending on the implementation, more or less than three levels of aggressiveness may be supported.

If the sensor quality metric indicates quality worse than Low quality, or indicates an erroneous value, then the process **2000** may generate an appropriate alert, message, or notification regarding the need to investigate, take corrective action, or the like (task **2036**). For example, the insulin infusion device may generate an audible alert and display a message that asks the user to check the integrity of the sensor device, recalibrate the sensor device, replace the sensor device, etc.

An iteration of the process **2000** can be performed as often as needed in an ongoing manner. In some embodiments, the process **2000** is performed for each new SG value (and its corresponding sensor quality metric).

Techniques and technologies may be described herein in terms of functional and/or logical block components, and with reference to symbolic representations of operations, processing tasks, and functions that may be performed by various computing components or devices. Such operations, tasks, and functions are sometimes referred to as being computer-executed, computerized, software-implemented, or computer-implemented. It should be appreciated that the various block components shown in the figures may be realized by any number of hardware, software, and/or firmware components configured to perform the specified functions. For example, an embodiment of a system or a component may employ various integrated circuit components, e.g., memory elements, digital signal processing elements, logic elements, look-up tables, or the like, which may carry out a variety of functions under the control of one or more microprocessors or other control devices.

When implemented in software, firmware, or other form of executable program instructions, various elements of the systems described herein are essentially the code segments or instructions that perform the various tasks. In certain embodiments, the program or code segments are stored in a tangible processor-readable medium, which may include any medium that can store or transfer information. Examples of a non-transitory and processor-readable medium include an electronic circuit, a semiconductor memory device, a ROM, a flash memory, an erasable ROM (EROM), a floppy diskette, a CD-ROM, an optical disk, a hard disk, or the like.

The various tasks performed in connection with a process described herein may be performed by software, hardware, firmware, or any combination thereof. It should be appreciated that a described process may include any number of additional or alternative tasks, the tasks shown in a flow chart representation need not be performed in the illustrated order, and that a described process may be incorporated into a more comprehensive procedure or process having additional functionality not described in detail herein. Moreover, one or more of the illustrated tasks could be omitted from an embodiment of the described process as long as the intended overall functionality remains intact.

While at least one exemplary embodiment has been presented in the foregoing detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the exemplary embodiment or embodiments described herein are not intended to limit the scope, applicability, or configuration of the claimed subject matter in any way. Rather, the foregoing detailed description will provide those skilled in the art with a convenient road map for implementing the described embodiment or embodiments. It should be understood that various changes can be made in the function and arrangement of elements without departing from the scope defined by the claims, which includes known equivalents and foreseeable equivalents at the time of filing this patent application.

What is claimed is:

1. A processor-implemented method comprising:

obtaining a current sensor-generated value that is indicative of a physiological characteristic of a user of a medical device, the current sensor-generated value produced in response to operation of a continuous analyte sensor device;

obtaining a sensor quality metric that indicates accuracy of the current sensor-generated value;

causing, in response to obtaining the sensor quality metric, configuration of a quality-specific operating mode of the medical device, the quality-specific operating mode comprising separate regulation of basal and bolus deliveries of a fluid medication based on the obtained sensor quality metric; and

causing regulation of fluid medication delivery from the medical device, in accordance with the current sensor-generated value and the quality-specific operating mode of the medical device.

2. The method of claim **1**, wherein the sensor quality metric is calculated from information generated by or derived from the continuous analyte sensor device.

3. The method of claim **2**, wherein the information comprises sensor age data, raw sensor signal values, and historical sensor-generated values produced in response to operation of the continuous analyte sensor device.

4. The method of claim **1**, further comprising managing generation of user alerts at the medical device in response to the obtained sensor quality metric.

5. The method of claim **4**, wherein managing generation of user alerts comprises:

generating user alerts when the obtained sensor quality metric satisfies alert-generating criteria; and

inhibiting the user alerts when the calculated sensor quality metric fails the alert-generating criteria.

6. The method of claim **1**, wherein:

the sensor quality metric is calculated by the continuous analyte sensor device;

the current sensor-generated value is obtained by the medical device; and

the method further comprises communicating the calculated sensor quality metric from the continuous analyte sensor device to the medical device.

7. The method of claim **1**, wherein obtaining the sensor quality metric comprises calculating the sensor quality metric based on:

sensor age data that indicate age of the continuous analyte sensor device;

measurement noise of raw signal output of the continuous analyte sensor device; and

changes in sensor-generated values that cannot be attributed to a natural physiological condition of the user.

8. The method of claim **1**, wherein when the sensor quality metric indicates an uncertain quality, the quality-specific operating mode enables automatic basal delivery by the medical device, disables an automatic bolus delivery feature of the medical device, and inhibits generation of any user alert related to the current sensor-generated value having uncertain quality.

9. The method of claim **1**, wherein when the sensor quality metric indicates high quality, the quality-specific operating mode enables automatic basal delivery by the medical device, enables an automatic bolus delivery feature of the medical device, and inhibits generation of any user alert related to the current sensor-generated value having high quality.

10. The method of claim **1**, wherein when the sensor quality metric indicates medium quality, the quality-specific operating mode enables automatic basal delivery by the medical device, enables a restricted automatic bolus delivery feature of the medical device, and inhibits generation of any user alert related to the current sensor-generated value having medium quality.

11. The method of claim **1**, wherein when the sensor quality metric indicates low quality, the quality-specific operating mode enables a safe basal delivery mode of the medical device, disables an automatic bolus delivery feature of the medical device, and generates a user alert to prompt the user to take corrective action.

12. The method of claim **11**, wherein the user alert prompts the user to calibrate the continuous analyte sensor device.

13. The method of claim **1**, wherein causing configuration of the quality-specific operating mode comprises causing adjustment of therapy actions of the medical device such that aggressiveness of fluid medication therapy is proportional to quality of the current sensor-generated value as indicated by the calculated sensor quality metric.

14. The method of claim **1**, wherein:

the medical device is an insulin infusion device;

the fluid medication comprises insulin;

the physiological characteristic of the user is a glucose level; and

the continuous analyte sensor device is a continuous glucose sensor device.

15. One or more non-transitory processor-readable media storing instructions which, when executed by one or more processors, cause performance of:

obtaining a current sensor-generated value that is indicative of a physiological characteristic of a user of a medical device, the current sensor-generated value produced in response to operation of a continuous analyte sensor device;

obtaining a sensor quality metric that indicates accuracy of the current sensor-generated value;

causing, in response to obtaining the sensor quality metric, configuration of a quality-specific operating mode of the medical device, the quality-specific operating mode comprising separate regulation of basal and bolus deliveries of a fluid medication based on the obtained sensor quality metric; and

causing regulation of fluid medication delivery from the medical device, in accordance with the current sensor-generated value and the quality-specific operating mode of the medical device.

16. A system comprising:

one or more processors; and

one or more processor-readable media storing instructions which, when executed by one or more processors, cause performance of:

obtaining a current sensor-generated value that is indicative of a physiological characteristic of a user of a medical device, the current sensor-generated value produced in response to operation of a continuous analyte sensor device;

obtaining a sensor quality metric that indicates accuracy of the current sensor-generated value;

causing, in response to obtaining the sensor quality metric, configuration of a quality-specific operating mode of the medical device, the quality-specific operating mode comprising separate regulation of basal and bolus deliveries of a fluid medication based on the obtained sensor quality metric; and

causing regulation of fluid medication delivery from the medical device, in accordance with the current sensor-generated value and the quality-specific operating mode of the medical device.

17. The system of claim **16**, wherein the sensor quality metric is obtained from the continuous analyte sensor device.

18. The system of claim **16**, wherein the medical device calculates the sensor quality metric from information generated by or derived from the continuous analyte sensor device, the information comprising:

sensor age data that indicate age of the continuous analyte sensor device;

measurement noise of raw signal output of the continuous analyte sensor device; and

changes in sensor-generated values that cannot be attributed to a natural physiological condition of the user.

19. The system of claim **16**, wherein:

when the sensor quality metric indicates an uncertain quality, the quality-specific operating mode enables automatic basal delivery by the medical device, disables an automatic bolus delivery feature of the medical device, and inhibits generation of any user alert related to the current sensor-generated value having uncertain quality;

when the sensor quality metric indicates high quality, the quality-specific operating mode enables automatic basal delivery by the medical device, enables the automatic bolus delivery feature, and inhibits generation of any user alert related to the current sensor-generated value having high quality;

when the sensor quality metric indicates medium quality, the quality-specific operating mode enables automatic basal delivery by the medical device, enables a restricted automatic bolus delivery feature, and inhibits generation of any user alert related to the current sensor-generated value having medium quality; and

when the sensor quality metric indicates low quality, the quality-specific operating mode enables a safe basal delivery mode of the medical device, disables the automatic bolus delivery feature, and generates a user alert to prompt the user to take corrective action.

20. The system of claim **16**, wherein causing configuration of the quality-specific operating mode comprises causing adjustment of therapy actions of the medical device such that aggressiveness of fluid medication therapy is proportional to quality of the current sensor-generated value as indicated by the sensor quality metric.

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